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(continued on next page)

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EP 1340511 A
EP 1310263 A
EP 0423817 A
WO 2000/056203 A
US 20020006887 A

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Other: **ONLINE: WPI, EPODOC, JAPIO**

(54) Abstract Title: **Decontamination system**

(57) A decontamination system suitable for decontaminating items of medical equipment such as endoscopes, the system comprising a plurality of pre-clean wipes, a two part sterilant system, and a plurality of rinse wipes. The two-part sterilant system comprises a first part comprising a reagent in a carrier medium and a second part which is miscible with the first part and which comprises a second reagent in a carrier medium. The first reagent will react with the second reagent when mixed to provide a sterilising composition. The first reagent preferably comprises sodium chlorite or sodium chlorate. The second reagent may comprise a solution of citric acid, boric acid, and sorbic acid. The reagents react to form chlorine dioxide in situ. The first part is contained in a dispenser 2 and the second part is adsorbed or impregnated in sterilising wipes (18, Fig. 2) which are contained in a sealed container 20. The first part is preferably contained within a pump dispenser or trigger-operated dispenser and dispensed as a fluid, foam, paste, powder, spray or a gel. The pre-clean wipes contain a surfactant which may comprise an enzyme. The rinse wipes contain an antioxidant such as sodium thiosulphate. Each wipe (pre-clean, sterilising and rinse) is contained in their own sealed sachet 20, 30, 40.

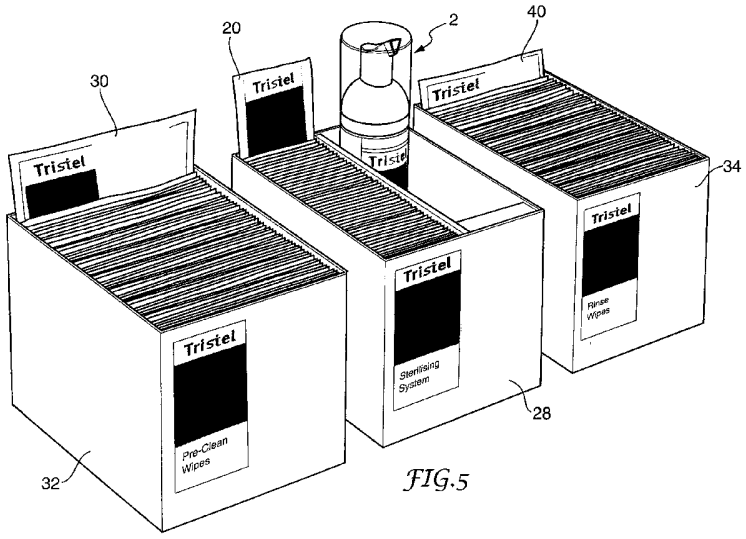

FIG.5

GB 2 413 765 A

GB 2413765 A continuation

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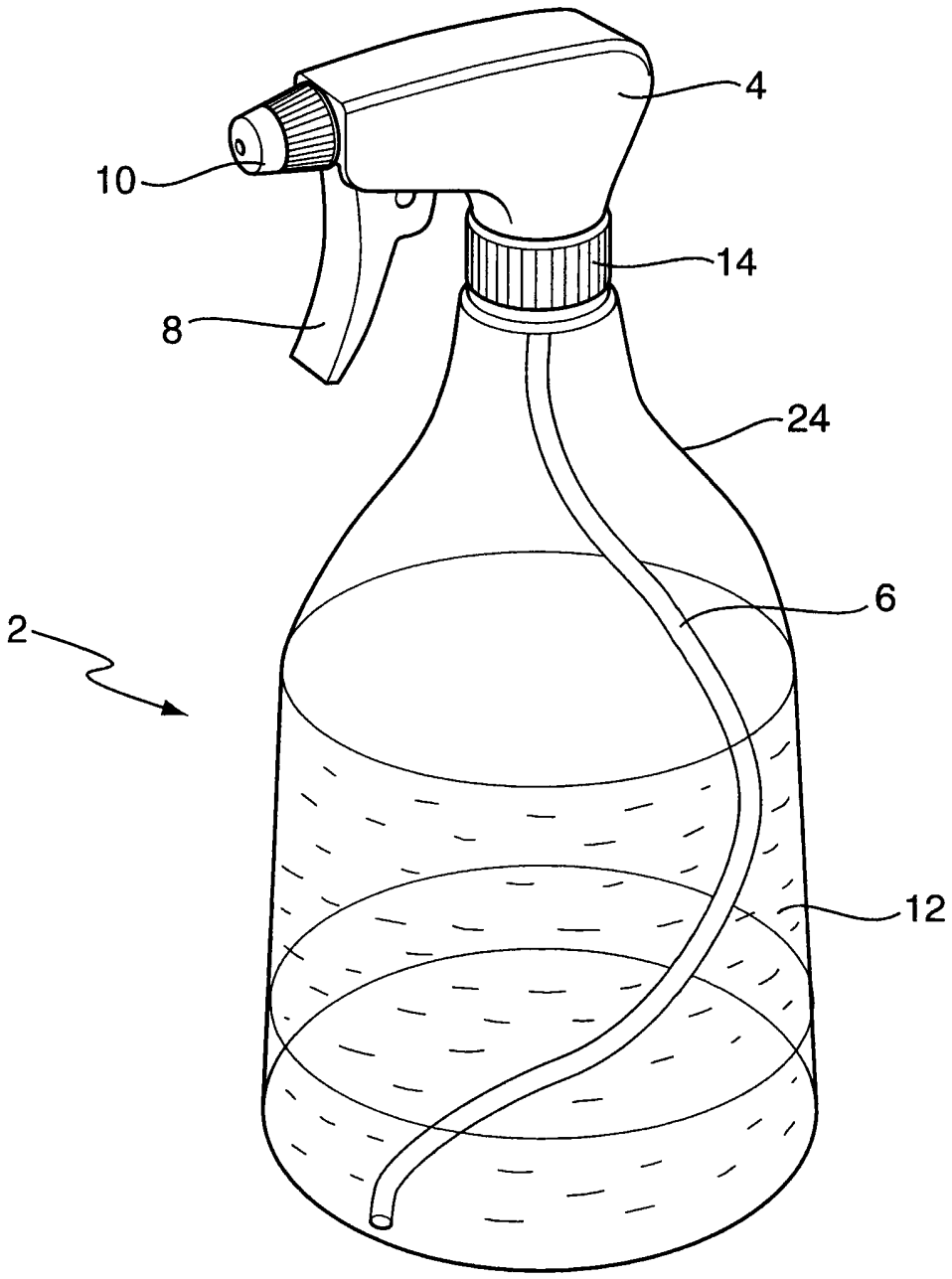

FIG.1

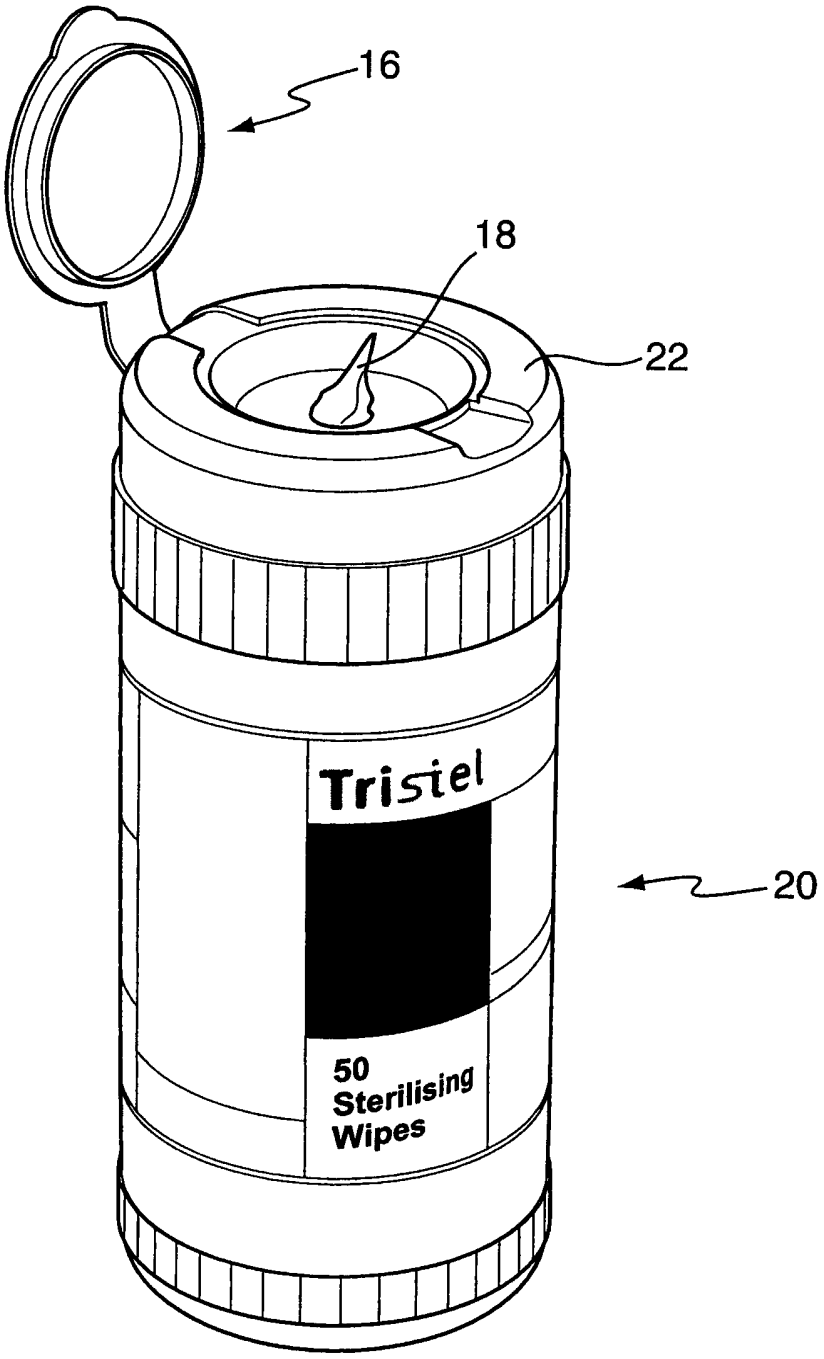

FIG.2

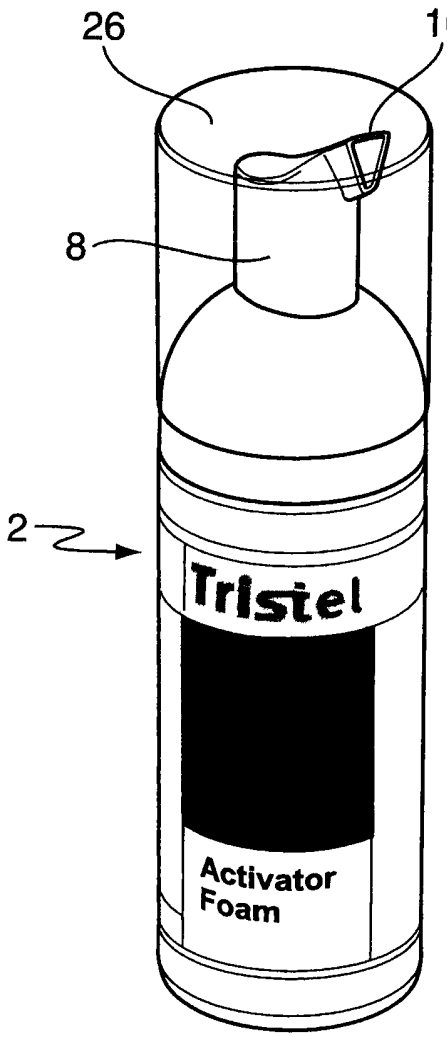
26
10
8
2
Tristel
Activator
Foam

FIG.3

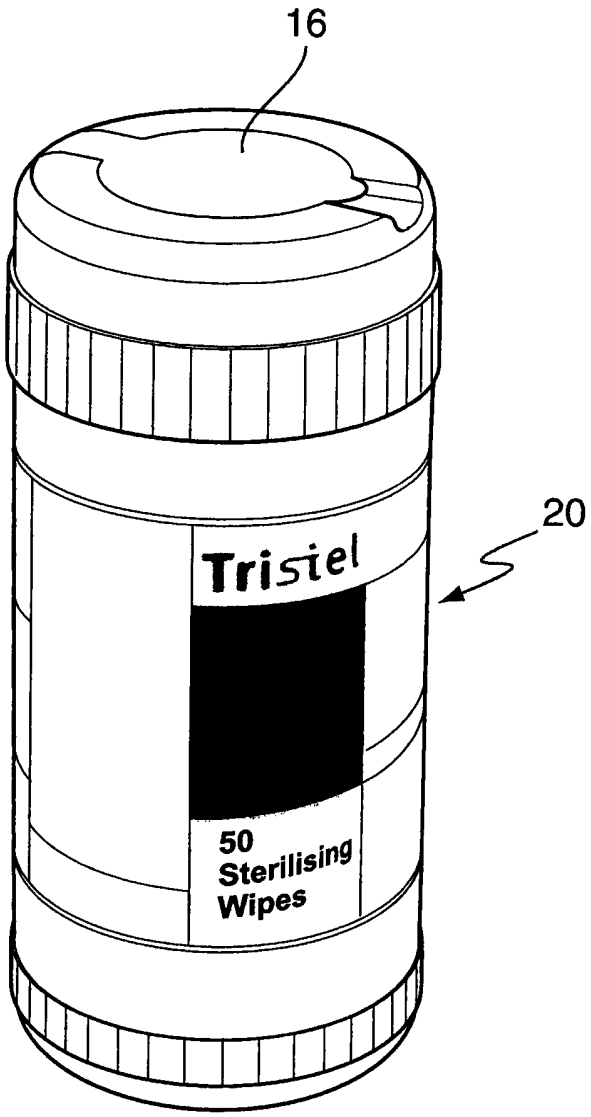
16
20
Tristel
50
Sterilising
Wipes

FIG.4

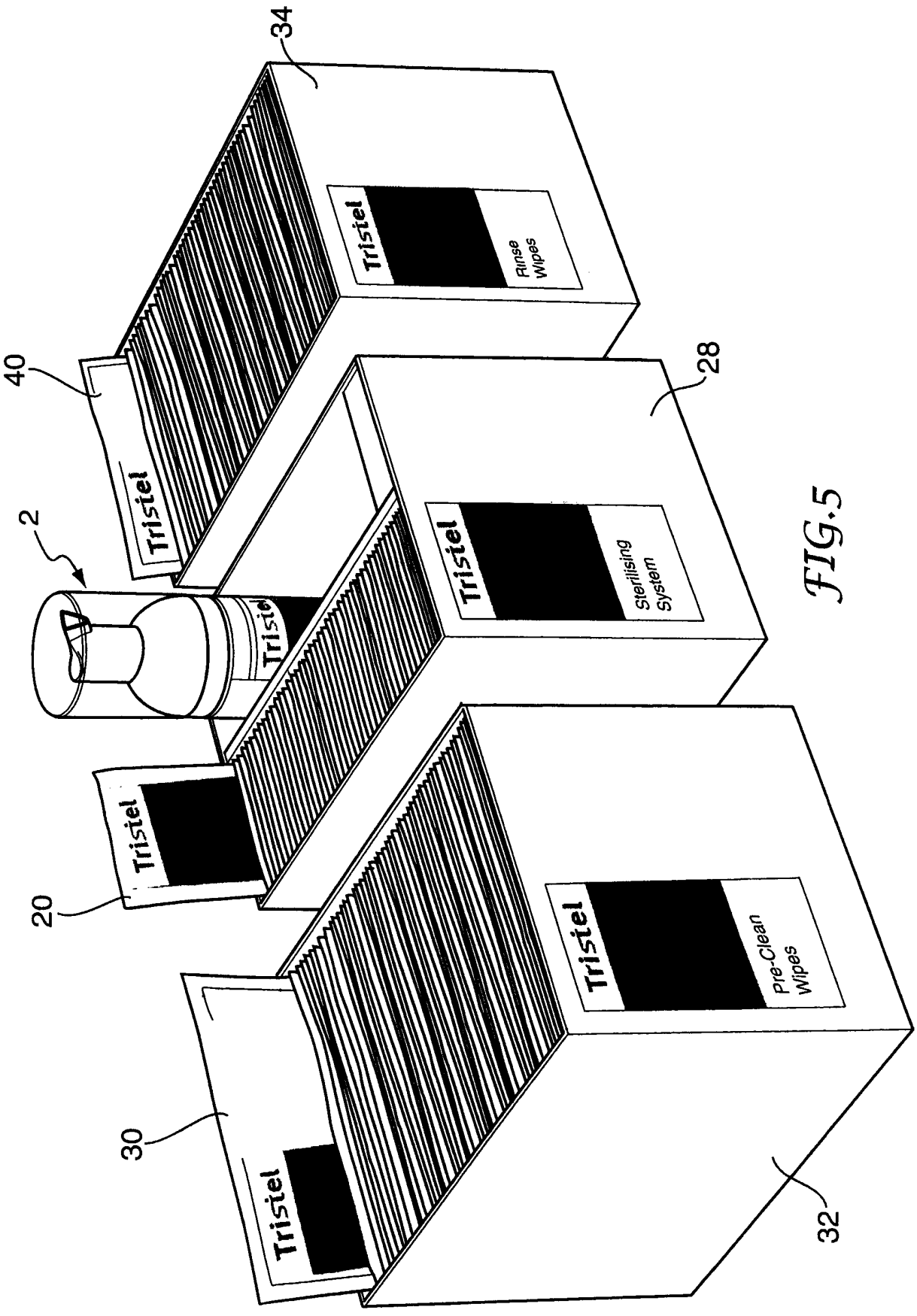
34
40
2
20
30
28
32
Tristel
Rinse Wipes
Sterilising System
Pre-Clean Wipes

FIG.5

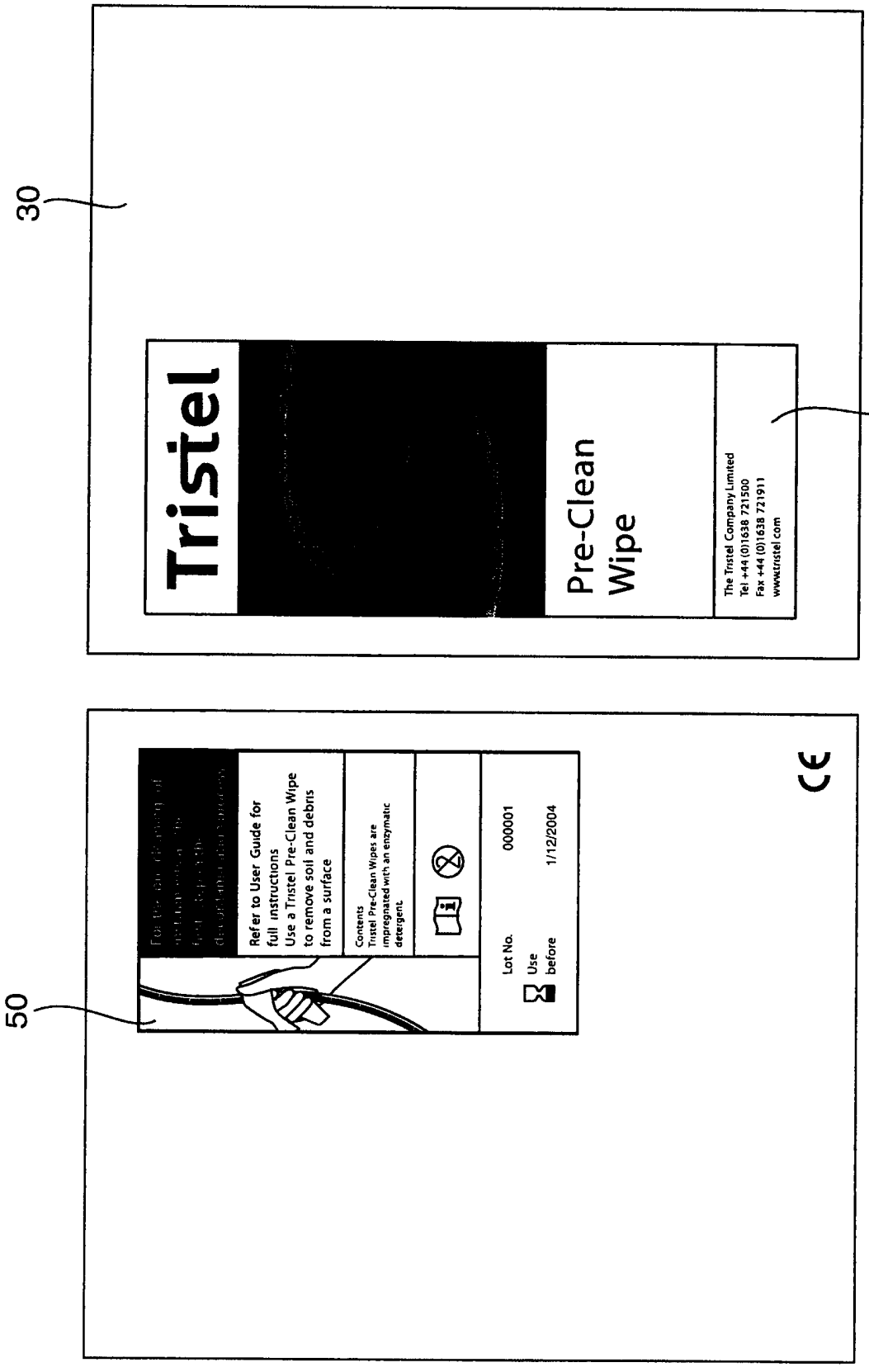
30
Tristel
Pre-Clean
Wipe
The Tristel Company Limited
Tel +44 (0)1638 721500
Fax +44 (0)1638 721911
www.tristel.com
48
50
Refer to User Guide for full instructions
Use a Tristel Pre-Clean Wipe to remove soil and debris from a surface
Contents
Tristel Pre-Clean Wipes are impregnated with an enzymatic detergent.
Lot No. 000001
Use before 1/12/2004
CE

FIG.6

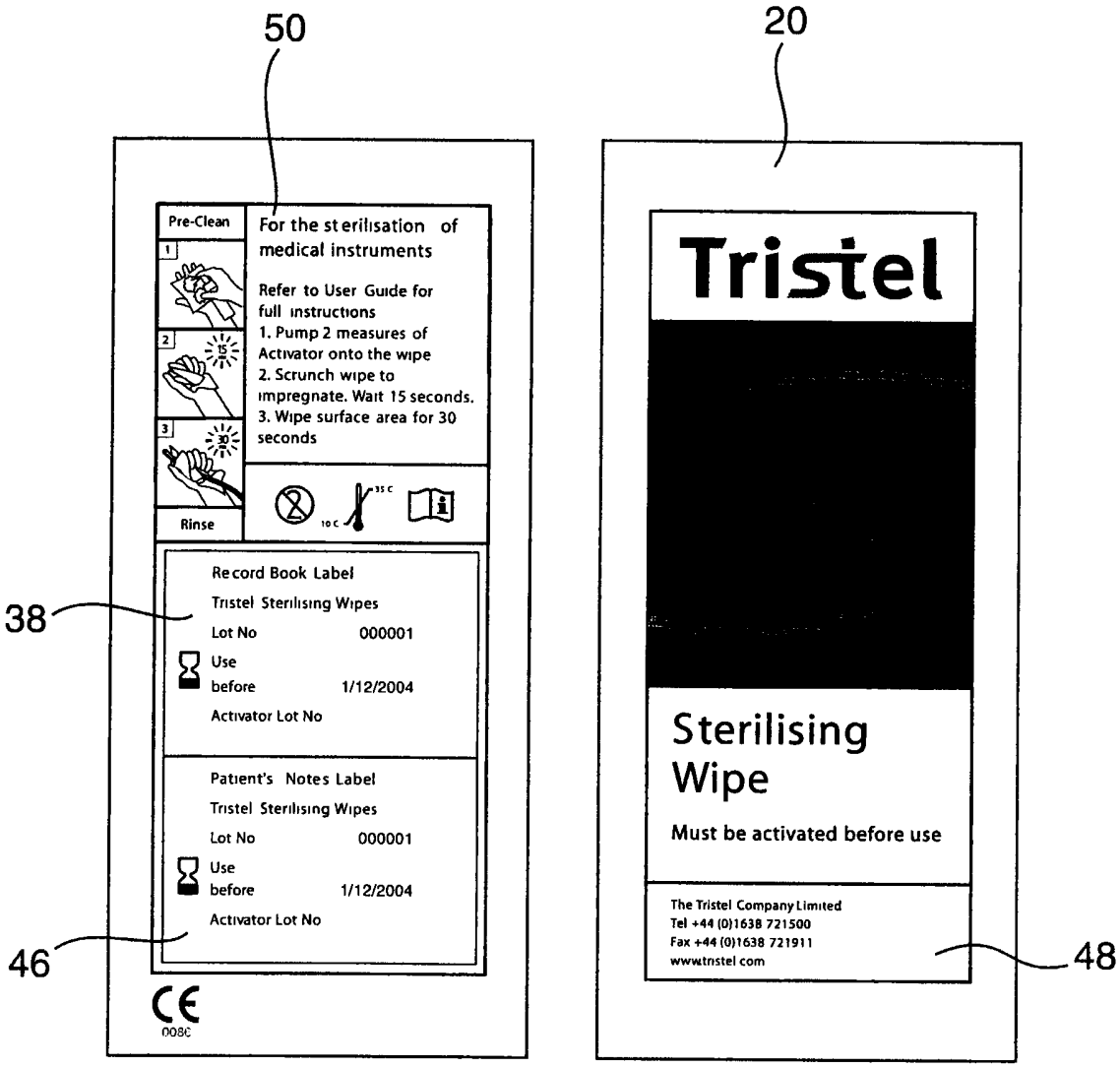
50
20
Pre-Clean
For the sterilisation of medical instruments
Refer to User Guide for full instructions
1. Pump 2 measures of Activator onto the wipe
2. Scrunch wipe to impregnate. Wait 15 seconds.
3. Wipe surface area for 30 seconds
Rinse
10C
35C
Record Book Label
Tristel Sterilising Wipes
Lot No 000001
Use before 1/12/2004
Activator Lot No
Patient's Notes Label
Tristel Sterilising Wipes
Lot No 000001
Use before 1/12/2004
Activator Lot No
38
46
CE
0086
Tristel
Sterilising Wipe
Must be activated before use
The Tristel Company Limited
Tel +44 (0)1638 721500
Fax +44 (0)1638 721911
www.tristel.com
48

FIG.7

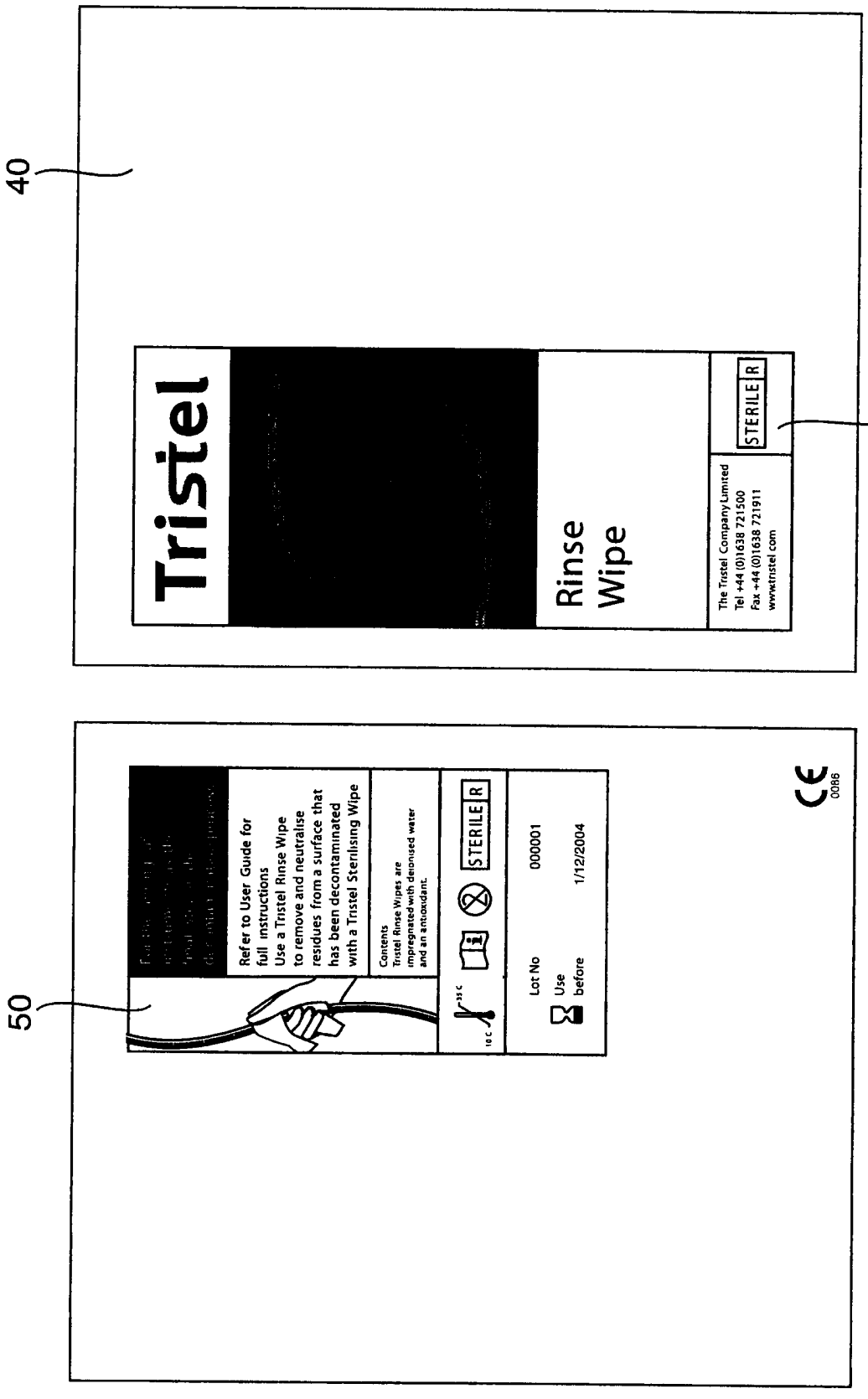
40
Tristel
Rinse
Wipe
The Tristel Company Limited
Tel +44 (0)1638 721500
Fax +44 (0)1638 721911
www.tristel.com
STERILE R
48
50
Refer to User Guide for full instructions
Use a Tristel Rinse Wipe to remove and neutralise residues from a surface that has been decontaminated with a Tristel Sterilising Wipe
Contents
Tristel Rinse Wipes are impregnated with deionised water and an antioxidant.
STERILE R
Lot No 000001
Use before 1/12/2004
CE
0086

FIG.8

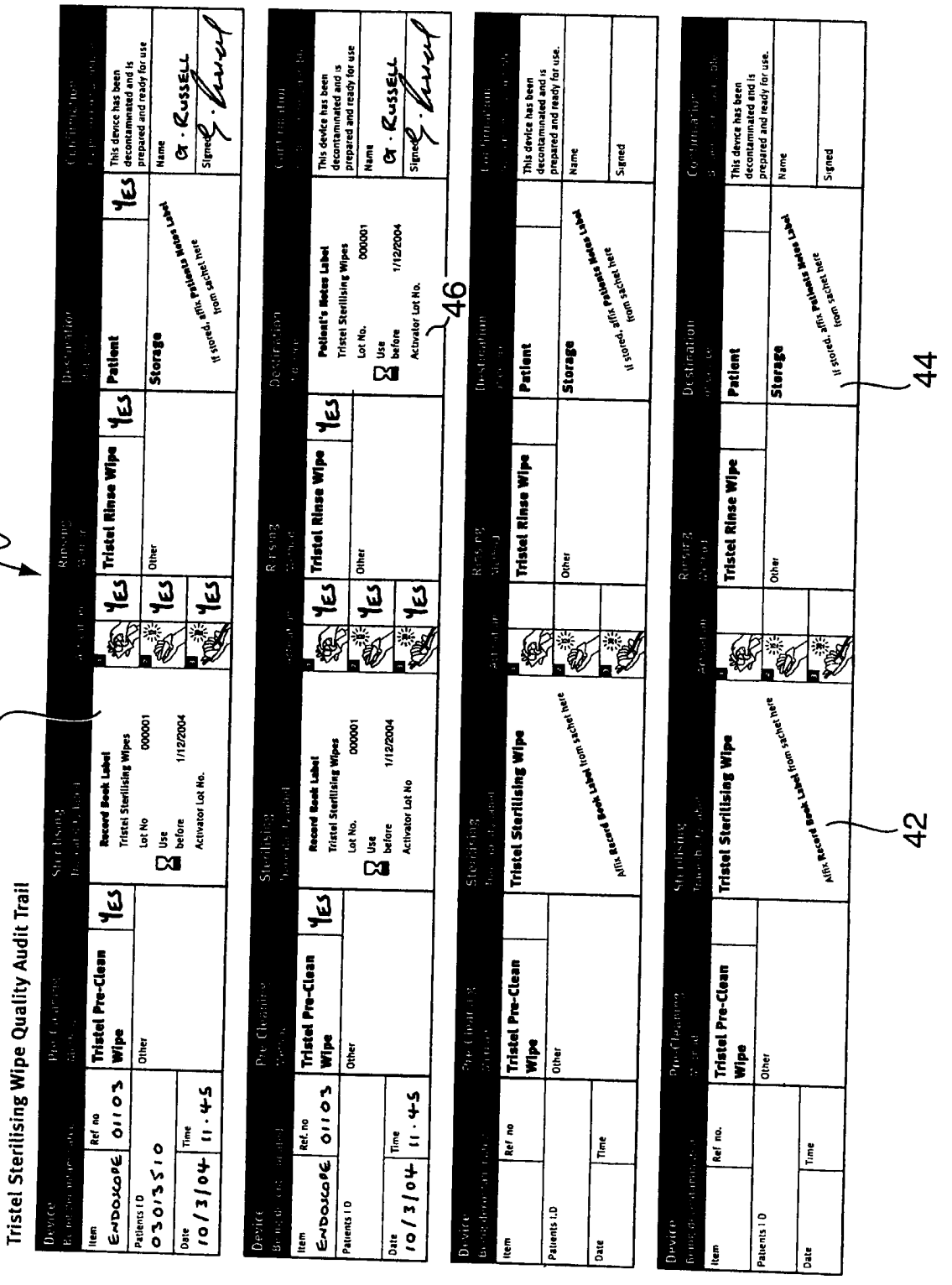
Tristel Sterilising Wipe Quality Audit Trail
36
38
42
44
46
Device
Pre-Cleaning
Sterilising
Rinsing
Destination
Confirmation
Item
Ref no
Endoscope
01103
Tristel Pre-Clean Wipe
Yes
Patients I.D
0301310
Other
Date
10/3/04
Time
11·45
Record Book Label
Tristel Sterilising Wipes
Lot No
000001
Use before
1/12/2004
Activator Lot No.
Tristel Sterilising Wipe
Affix Record Book Label from sachet here
Tristel Rinse Wipe
Patient
Storage
If stored, affix Patients Notes Label from sachet here
This device has been decontaminated and is prepared and ready for use
Name
Gr · Russell
Signed
Patient's Notes Label
Tristel Sterilising Wipes
Lot No.
000001
Use before
1/12/2004
Activator Lot No.
Signed

FIG. 9

DECONTAMINATION SYSTEM

FIELD OF THE INVENTION

The present invention relates to a decontamination system, notably to a system for ensuring that a medical device is made safe after use on one patient prior to use on another patient. The invention preferably makes use of chlorine dioxide (ClO_2) as a sterilant.

BACKGROUND TO THE INVENTION

"Traditionally, the word 'decontamination' has been applied to those cleaning procedures - automatic and/or manual - that take place prior to sterilisation. Recent documentation, however, has redefined the word to apply to the whole series of procedures to ensure that a device is made safe after use on one patient prior to use on a second. Decontamination can thus include cleaning, disinfecting and sterilising." This statement is taken from an article published in the ISSM (Institute of Sterile Service Managers) Journal, Vol. 5, No. 1 July-September 2000. The statement helps to explain what the decontamination process has come to mean in modern UK hospitals and goes on to refer to HTM2030, which has been the driver for change in processing many types of medical instruments. The term 'decontamination' will be used herein to refer to the above redefinition, including cleaning and sterilising.

Health Technical Memorandum (HTM) 2030 was introduced in 1993 and updated in 1997 and 2001 to improve the sterile processing performance of washer disinfectors. HTM2030

addresses the use of washer-disinfectors for instruments, many of which cannot be autoclaved, for example flexible endoscopes. In essence, it describes the need to wash instruments thoroughly before disinfection/sterilisation (by heat or by chemical); to be followed by the disinfection/sterilisation stage and to culminate, in the case of chemical disinfection, in the rinsing of the instrument. HTM2030 also addresses the need for the entire process to be recorded in a traceability and audit system.

Two-part sterilising solutions are used in applications where the active sterilising ingredient is unstable over time. The solution is therefore prepared *in situ* shortly before it is to be used. A particularly important sterilising agent is chlorine dioxide, which may be formed from mixtures of various reagents including: chlorite and acid; chlorate, peroxide and acid; and chlorite, hypochlorite, and a suitable buffer. Chlorine dioxide has excellent sterilising and bactericidal properties, and oral ingestion in man and animals has been shown to be relatively safe.

The cleaning of endoscopes and other medical equipment with suitable chlorine dioxide solutions is known. See, for example, European Patent Number 0 785 719 and United States Patent Numbers 5,696,046 and 6,007,772, the contents of which are hereby incorporated by reference.

It is not always convenient to mix up batches of solutions for use in sterilising equipment. For wiping down (rather than thoroughly cleaning inside and out) of endoscopes and probes, wipes of alcohol, general-purpose detergent, or soapy water are generally used, but these are not as effective as

chlorine dioxide. It is desirable to be able readily to make up small quantities of two-component sterilising agents when desired and to be able to make such agents up in a form in which they may be readily handled for a particular application. It is particularly desired to provide a decontamination system which meets the HTM2030 standard.

SUMMARY OF THE INVENTION

According to a first aspect of the present invention there is provided a decontamination system suitable for decontaminating items of medical equipment such as endoscopes, the system comprising:

(I) a plurality of pre-clean wipes comprising moist fabric members for wiping an item to be decontaminated;

(II) a two-part sterilant system comprising:

(a) a first part comprising a first reagent in a carrier medium; and

(b) a second part which is miscible with the first part and which comprises a second reagent in a carrier medium;

wherein the first reagent and the second reagent will react when mixed to provide a sterilising composition;

the first part being contained in a dispenser whereby it may be dispensed as a fluid, and the second part being absorbed or impregnated in a plurality of sterilising wipes each of which comprises a fabric member in a sealed container; and

(III) a plurality of rinse wipes, each rinse wipe comprising a moist, sterile, fabric member in its own sealed container.

The system enables an item such as a flexible endoscope to be

decontaminated without the use of a conventional washer-disinfector and, indeed, without a water supply. Each of the three wipes performs one stage of the decontamination process. The chemistry of the rinse wipe may be tailored or selected to give optimal surface rinsing for a given sterilant system. For example, the rinse wipe may include an agent for neutralising an active ingredient of the sterilant system ('sterilising wipe'). In a preferred embodiment the sterilising wipe has ClO_2 as the active ingredient and the rinse wipe contains an antioxidant such as sodium thiosulphate for neutralising excess of ClO_2.

In prior art decontamination processes, ie, in washer-disinfectors, which use filtered mains water or water produced by reverse osmosis, or in a manual procedure in which tap water or bottled sterile water may be used, the water is indiscriminate to the chemistry employed in the disinfection process. Consequently the sterilant may be insufficiently removed by rinsing, or an undesirable excess of rinse water may be required.

The fabric members may be formed from any suitable fabrics, either woven or non-woven. They may be of natural or man-made fibres, for example polyester, cotton, cellulose or mixtures thereof. Other suitable fabrics will be well known to those skilled in the textile or fabric arts. The fabric members for each of the three types of wipe may be same or different from each other.

Pre-Clean Wipe

The pre-clean wipe is moist and preferably provided in a

sealed container. The container may be resealable, for example a canister with a lid, or a resealable sachet. In a preferred embodiment, each pre-clean wipe is provided in its own sachet which may be factory-sealed and disposed of after use.

It is preferred that the pre-clean wipe contain additional components to improve its efficiency. The wipe may contain at least one surfactant to promote wetting and/or dissolution of organic deposits. The surfactant may be a foaming surfactant such as a detergent or a soap, or a low-foam non-ionic surfactant such as Lanawet LF-6. The pre-clean wipe may advantageously contain other agents, for example one or more selected from the following: enzymes for digesting or solubilizing organic deposits, humectants, buffers, preservatives, corrosion inhibitors, solvents, or anti-foaming agents.

Sterilant System

The term 'fluid' is used herein to include liquids, foams, sprays, pastes, aerosols, powders, sols and gels. It is particularly preferred that the first part of the sterilant system is dispensed as a foam or a spray to facilitate its coverage of a desired area of the fabric member. Optionally, the dispenser may have a relatively large dispensing head, for supplying the fluid over all or a substantial part of a surface of the fabric member. For example, the dispensing head may take the form of a rose or sprinkler with a multitude of small orifices to spread the fluid over the fabric member.

The dispenser is preferably a pump-dispenser, notably a trigger-operated dispenser, both for convenience and to facilitate the dispensing of metered quantities. However, other pump dispensers could be used, for example, a squeeze bottle with a suitable spray or foam nozzle. The invention will, for convenience, be described hereinafter with reference to the use of a trigger-operated dispenser, but it is to be understood that it is not limited to this embodiment.

By putting up the first part in a trigger-operated dispenser, small quantities may be readily dispensed without risk of spillage. Preferably the dispenser comprises a sprayer apparatus that provides the first part as a foam so that it is at least partly form-retaining and can be readily seen and manipulated. We have also found that providing the first part in a foam may have the beneficial effect of reducing the odour of chlorine dioxide when the wipe is activated. The invention will for convenience be described with reference to this preferred embodiment, but it will be understood that the invention is not limited to this embodiment.

The trigger sprayer may include a mixing chamber to facilitate mixing of the first part with air, for example as described in United States patent number 5,337,929.

By providing the second part absorbed in a fabric wipe, a sterilising wipe may readily be prepared by applying the first part to the fabric wipe. The user may fold the wipe or rub two halves together to facilitate mixing. The wipes are particularly useful for cleaning, disinfecting, and sterilising surfaces and equipment, notably in a medical

environment.

The first part may include a coloured component so that a visual indication of the coverage of the wipe with the first part can be made.

In a preferred embodiment, at least one of the first and second parts is provided with an indicator reagent that changes colour to show that sufficient mixing has taken place. Where the first part and the second part are of different pH, the indicator may be a pH-sensitive indicator. Suitable indicators are well known to those skilled in the art, non-limiting examples including: phenol red, litmus, thymol blue, pentamethoxy red, tropeolin OO, 2,4-dinitrophenol, methyl yellow, methyl orange, bromophenol blue, tetrabromophenol blue, alizarin sodium sulphonate, α-naphthyl red, p-ethoxychrysoidine, bromocresol green, methyl red, bromocresol purple, chlorophenyl red, bromothymol blue, p-nitrophenol, azolitmin, neutral red, rosalic acid, cresol red, α-naphtholphthalein, tropeolin OOO, phenolphthalein, α-naphtholbenzein, thymolphthalein, nile blue, alizarin yellow, diazo violet, tropeolin O, nitramine, Poirrer's blue, trinitrobenzoic acid, and mixtures thereof. It is preferred that the indicator is selected so that both parts are separately colourless and the colour develops when the two parts are mixed.

Alternatively, or additionally, one or more fluorescent additives may be included so that the mixture fluoresces to indicate mixing. Non-limiting examples of suitable fluorescing agents include: 4-methylumbelliferone, 3,6-dihydroxanthone, quinine, thioflavin, 1-napthol, harmine,

coumarin, acridine orange, cotarmine, and mixtures thereof.

The indicator (colour change or fluorescent) may be included in either part. Preferred proportions by weight are about 0.1 to 10%, notably about 0.5 to 2%.

The carrier mediums may be fluids such as liquids or sols, or they may be more form-retaining or viscous compositions such as gels or pastes. It is preferred that at least one reagent is present in an aqueous fluid, although other additives may of course be present. Preferably both reagents are put up in aqueous fluids.

The trigger-operated dispenser may be a conventional atomizer or foamer, or other manual pump in which the contents are expelled manually by operation of the trigger by the user. Alternatively, the dispenser may contain a propellant to dispense the contents when operation of the trigger opens a valve, as is well known in applications such as shaving foam canisters and the like. Suitable dispensers will be well known to those skilled in the art.

The preferred sterilising agent is chlorine dioxide, which may be formed from suitable known reagents. In a preferred embodiment one reagent is a chlorite (notably sodium chlorite) and the other is an acid, preferably with a buffer. Suitable acids include lactic acid, citric acid, boric acid, phosphoric acid, acetic acid, sorbic acid, ascorbic acid, hydrochloric acid or mixtures thereof. In a preferred embodiment a mixture of acids is used, notably a mixture of citric, sorbic and boric acids.

A particularly preferred system is as described in EP 0 785 719, with the corrosion inhibitors optionally not included, and with other additives as desired for particular applications. In addition to suitable indicators, optional additives include foam-promoting agents or stabilizers, humectants, essential oils and fragrances. Other sterilising agents may also be employed; for example chlorine or oxygen. Chlorine may be produced by reaction between a hypochlorite such as sodium hypochlorite, and a suitable acid or buffer. Oxygen may be produced by reaction between a peroxide and a catalyst such as catalase, optionally in the presence of a buffer. For convenience hereinafter, the invention will be described with reference to chlorine dioxide as the sterilising agent.

Suitable foam promoters will be well known to those skilled in the art. Non-limiting examples include: sodium laureth sulphate, ammonium lauryl sulphate, cocamide DEA, cocamidopropyl betaine, sodium lauryl sarcosinate, cocamidopropylamine oxide, monoethanolamine lauryl sulphate, cocamidopropyl hydroxysultaine, cocoyl sarcosinate. Anionic, cationic, non-ionic and amphoteric surfactants may be employed depending on the chemistry of the reagents. The foam promoters are selected to provide a stable foam structure. The foam promoter may comprise from about 0.1 to 50% by weight of the first part, notably from about 1 to 10%, preferably from about 3 to 6%.

Suitable foam stabilizers well known to those skilled in the art may also be used, in proportions similar to those for the foam-promoters. Non-limiting examples include: alkanolamides, for example monoethanolamides and

diethanolamides, amine oxides, betaines, protein hydrolysates and cellulose derivatives such as carboxymethylcellulose.

In a preferred embodiment, a humectant is included in at least one of the first and second parts. Humectants serve to reduce the rate of evaporation of components and improve product feel if direct skin contact is involved. We have found that the use of a humectant reduces the volatility of chlorine dioxide, which reduces the odour of chlorine dioxide and prolongs the life of the activated mixture. Non-limiting examples of suitable humectants include sodium lactate and polyols, for example glycerine, sorbitol, propylene glycol, diethylene glycol and ethylene glycol. The humectant may be present in any desired amount, particularly from about 0.1 to 50% by weight, notably from about 0.5 to 10%, preferably from about 1 to 3%.

Where one of the reagents is basic or oxidising, for example sodium chlorite, it is particularly preferred that this reagent is provided in the trigger dispenser rather than in the wipe, because such reagents may react with the fabric over time. Preferably the optional humectant is included in the first part, with the sodium chlorite or other first reagent.

The first and/or second part may further include a biocide to ensure that, in the event of poor mixing of the parts, a biocidal effect is still present. The first and/or second part may also include a preservative.

Equal weights of the first part and the second part may provide, when mixed, a sterilising composition having a pH of

from 1.0 to 10.5, but it is preferred that the composition has a pH of from 4.5 to 6.5 as this may result in a more stable compound.

A plurality of fabric members may be provided in a single resealable container, for example a canister with a lid, or a resealable sachet. In a preferred embodiment, each fabric member is provided in its own sachet which may be factory-sealed and disposed of after use. In a particularly preferred embodiment, each sealed sachet contains a single fabric wipe and carries a removable adhesive label on its outer surface, the label containing information about the provenance of the wipe, for example its lot or batch number, its date of manufacture, or its expiry date. The label may be affixed to a record sheet and used as part of an audit trail to provide a record that an item of equipment has been properly decontaminated and the date on which this was done. In one embodiment the label adhesive and the record sheet are selected so that, though the label is releasably adhered to the sachet, it will become permanently adhered to the record sheet and cannot be removed intact. This arrangement helps provide a permanent validation record of the decontamination process. The record sheet may be provided in any convenient form, for example as a single sheet, as part of a loose-leaf binder, or in an audit trail book.

It will be understood that the sterilant system may optionally be provided as a stand-alone sterilant system, for use without the pre-clean wipe or the rinse wipe, or for use as a replacement component in the decontaminant system.

Rinse Wipe

To maintain sterility of the wipes it is preferred that each fabric member is provided in its own sachet which is factory-sealed and disposed of after use. The sachets may be gamma-irradiated before or after sealing to ensure sterility.

In addition to water (preferably deionised water), optional components may comprise an antioxidant to neutralise oxidant in the sterilant system, a sequestering agent to sequester metal salts and improve cleaning, and a lubricant to provide visual enhancement, or 'shine' to a decontaminated item such as an endoscope. A preservative may optionally be included, to eliminate toxic residues and enhance product stability prior to gamma-irradiation.

Other aspects and benefits of the invention will appear in the following specification, drawings and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be further described, by way of example, with reference to the following drawings in which:

Figures 1 and 3 show views of alternative embodiments of pump dispensers for use in a decontamination system in accordance with embodiments of the present invention;

Figures 2 and 4 are perspective views of a canister of sterilising wipes for use in a decontamination system in accordance with embodiments of the present invention;

Figure 5 shows a decontamination system in accordance with another embodiment of the invention;

Figures 6 to 8 illustrate sachets from the system of Figure 5; and

Figure 9 shows a record sheet for use with the decontamination system of Figure 5 in accordance with a further embodiment of the invention.

DETAILED DESCRIPTION

The pump dispenser 2 shown in Figure 1 is a trigger sprayer of a construction well known *per se*. The dispenser 2 comprises a body 24 connected to a sprayer head 4 by an internally screw-threaded connector ring 14. A spray nozzle 10 in the head is connected to an aqueous liquid 12 by means of a dip tube 6. A user dispenses the liquid 12 through the nozzle 10 by operation of a trigger 8. Rotation of the

nozzle allows the user to dispense the fluid as either a spray of fine droplets or as a foam.

In the present example, the liquid 12 (first part) comprises 0.75% of a first reagent (sodium chlorite), 3.0% foam promoter (Cocamidopropyl Betaine). The remainder is deionised water. In this specification, all parts are by weight unless otherwise indicated. Operation of the trigger 8 dispenses the first part 12 as a foam.

An alternative design of pump dispenser 2 is illustrated in Figure 3. The trigger 8 is formed integrally with the nozzle 10. Depressing the trigger 8 dispenses a portion of the fluid contents as a foam (referred to as the 'Activator Foam' because it activates the sterilising powers of a sterilising wipe). A protective cap 26 is provided to cover the nozzle 10 and trigger 8 when not in use.

Turning now to Figures 2 and 4, a sealable container 20 is also of a construction well known *per se*. The container 20 is a hollow cylinder fitted with a cap 22. The container 20 contains a roll of interleaved fabric sheets (or 'sterilising wipes') 18. In this example, the fabric sheets 18 are to be used as sterilising wipes, but it will be understood that the sheets 18 could also be used for other applications such as biocidal wound-dressings.

The cap 22 has a central opening through which a tip of the central wipe 18 is disposed. By pulling the central wipe 18, a user may remove this wipe from the container, leaving the next wipe in its place. A stopper 16 is provided on the cap 22 for releasably sealing the container 20.

In this example, the wipes 18 are impregnated with an aqueous acid solution (second part). In this example, the acid solution comprises 0.5% citric acid, 0.05% sorbic acid, 0.05% boric acid. The solution also comprises 0.35% of a buffer (trisodium phosphate). The solution also comprises 0.25% trisodium citrate, 1.0% glycerine, 0.1% benzotriazole, 0.1% sodium molybdate and 0.3% sodium nitrate. The remainder is deionised water.

The pump dispenser 2 and container 20 together comprise the sterilant system. To activate a sterilising wipe, a user removes the wipe 18 from the container 20, and applies a portion of foam from the dispenser 2 to the wipe 18. To facilitate mixing of the reagents in the foam and the wipe, the user may fold the wipe in half and crush or rub the folded wipe before opening it out. Preferably, one of the components is provided with a pH-sensitive indicator which changes colour or becomes coloured when adequate mixing has occurred, thereby indicating that sufficient ClO_2 has been generated in the wipe.

Once the sterilising wipe has been activated, it may be used for a number of applications, including wiping surfaces and sterilising medical equipment such as endoscopes.

The sterilant system illustrated in Figures 1-4 may be accompanied by a plurality of pre-clean wipes and a plurality of rinse wipes for treatment of an item to be decontaminated respectively before and after treatment with a sterilising wipe. Each wipe may be made from the same fabric and may have the same dimensions. All of the wipes may be identical

except for the fluid with which they are impregnated or soaked.

In the preferred embodiment illustrated in Figures 5-8, each sterilising wipe is provided in its own sealed container 20, in this example a sachet. The disinfectant system comprises a box 32 of pre-clean wipes in sachets 30, a box 28 of sterilising wipes in sachets 20, and a box 34 of rinse wipes in sachets 40. Each sachet 20, 30, 40 is factory-sealed and may be disposed of after the wipe has been removed. The foam pump dispenser 2 is also provided in the box 28 of sterilising wipe sachets 20

Each sachet 20, 30, 40 is provided with a label 48 on the front, identifying what the relevant wipe is for. A label 50 on the back gives information about how the wipe is to be used and other product details.

In this example, the pre-clean wipes contain the fluid formulation set forth in Table 1.

Ingredients	**%w/w**	**CAS No.**
Deionised water	93.285	7732-18-5
Trisodium citrate	0.5	68-04-02
Sodium benzoate	0.2	532-32-1
Isopropanol	1.5	67-63-0
Monopropylene glycol	3.0	57-55-06
Glycol ethers (Downal DDNP grade)	1.0	029911-27-1
Alcalase	0.2	9014-01-1
Termamyl	0.02	9000-90-2
Lipolase	0.02	9001-61-1
Surfactant LF6 (low-foam)	0.1	107600-33-9

Phenoxyethanol (preservative)	0.15	26172-55-4
Silicone emulsion (antifoamer)	0.025	

PRE-CLEAN WIPE FORMULATION

TABLE 1

The trisodium citrate functions as a buffer; sodium benzoate functions as a preservative and corrosion inhibitor; monopropylene glycol functions as a humectant and solubiliser; the enzymes promote digestion and solubilizing of organic deposits.

The fluid formulation for the rinse wipes is given in Table 2.

Ingredients	**%w/w**	**CAS No.**
Deionised water	97.25	7732-18-5
Sodium thiosulphate	0.5	7772-98-7
EDTA (sodium salt)	0.1	139-33-3
Silicone emulsion (Dow 365)	2.0	
Phenoxyethanol (preservative)	0.15	26172-55-4

RINSE WIPE FORMULATION

TABLE 2

Sodium thiosulphate is an antioxidant which helps to remove traces of ClO_2 from an item that has been sterilised. EDTA sodium salt is a sequestrant for removing dissolved metal salts and improving cleaning. The silicone emulsion functions as a lubricant to help 'shine' an item such as an endoscope and provide visual enhancement. The preservative is added before the rinse wipes are gamma-irradiated, to help

reduce or eliminate toxic residue and enhance product stability prior to irradiation.

To decontaminate an item (in this example an endoscope), a user first opens a pre-clean wipe sachet 30 and takes out the pre-clean wipe. This wipe is used to remove soil and debris from the surface of the endoscope, in accordance with instructions on the label 50 of the sachet 30. After pre-cleaning, the pre-clean wipe is disposed of, and the user activates a sterilising wipe 18 by removing it from its sachet 20 and applying a metered dose of foam from the dispenser 2 (in this example, two measures of foam activator are applied in accordance with instructions on the label 50 on the back of the sachet 20). After manipulating the wipe 18 to ensure mixing of the activator foam and the fluid in the wipe 18, the user waits about 15 seconds and then wipes the surface of the endoscope for about 30 seconds. Finally, a rinse wipe sachet 40 is opened and a rinse wipe is used to wipe down the surface of the endoscope. The endoscope is now decontaminated and ready for use.

Referring now to Figure 9, a record sheet 36 is illustrated for use in providing a quality audit trail for an item of equipment decontaminated with an embodiment of the system of the present invention. The record sheet 36 may be loose or it may be bound in a book or file. The record sheet carries boxes or other defined locations for recordal of information relating to the decontamination of the item. In the present example spaces are defined for recording the type of device to be decontaminated, its reference number, its method of decontamination, and other details including the ID number of the patient on which the device has most recently been used,

the date and time of decontamination, and the name and signature of the responsible person. The record sheet permits recording of the pre-clean wipe process, the sterilising process, and the rinse wipe process. It also provides information as to the immediate destination of the decontaminated item - either for use with the patient or return to storage.

For each decontamination history of each device on the record sheet 36 there is provided a space 42 for receiving a record book label 38 from the back of the sterilising wipe sachet 20. The user peels the sticky label 38 off the sachet and affixes it in the space 42 as proof that the sterilising wipe 18 has been used, and marks adjacent boxes to confirm that the wipe 18 has been properly activated by following the specified steps. If the decontaminated device is to be returned for use on the specified patient, this information is recorded on the record sheet. Alternatively, if the device is to be returned to storage, a second sticky label, the 'patient's notes label' 46 is peeled off the sterilising wipe sachet 20 and affixed in another box 44 on the record sheet 36. This embodiment of the invention therefore provides a traceability system which uses the sterilising wipe sachet 20 as evidence that the wipe has been used as a single-use process, uniquely identified to a specific instrument at a specific time and date.

EXPERIMENTAL RESULTS

Experiment 1

Sterising wipes 18 in accordance with one aspect of the

invention were tested and compared with conventional wipes saturated with isopropanol (IPA), a general-purpose detergent, and sterile deionised water.

The test method to evaluate effectiveness of the wipes in killing/removing test organisms dried onto test surfaces, involved the following steps.

1. Mark out a six inch (30.5 cm) square test area on the test surface.

2. Inoculate the test surface with 0.5 ml of test organism suspension.

3. Spread the inoculum over the test area using a plastic spreader.

4. Allow the inoculum to dry (about 30 minutes).

5. Don a pair of disposable plastic gloves.

6. Prepare a ClO_2 wipe in accordance with the invention, using a prescribed mixing time.

7. Wipe the test area for the prescribed wiping time.

8. Place the wipe in 10 ml of universal neutraliser in a Universal bottle (Test Suspension A). Vortex stir to release organisms.

9. Wipe the entire test area with a cotton-tipped swab (thoroughly/10 times).

10. Dip the swab into 10 ml of universal neutraliser in a Universal bottle after each sampling of the test area and rotate the swab against the inner wall of the bottle to release organisms (Test Suspension B).

11. Prepare 5 serial deci-dilutions of Test Suspension A and Test Suspension B in diluent.

12. Inoculate 0.5 ml of each dilution onto a culture plate and spread using a plastic spreader. Incubate the plates and do a viable count.

13. Calculate $\log_{10}$ reductions achieved from the difference in the initial inoculum and the number of test organisms recovered after disinfection with a ClO_2 wipe.

Test variables were as follows.

Test Surface

A flat stainless steel instrument tray.

Test Organism

Spores of Bacillus subtilis var.niger NCTC 10073 freshly prepared by the method of Beeby & Whitehouse.

Inoculum

The test surface was inoculated with 1 X 10^8 spores.

Suspending Fluid

Sterile deionised water.

Disinfectant Concentrations

1. 200 ppm ClO_2 (notional)
2. 300 ppm ClO_2 (notional).

Mixing Times

15 + 30 seconds.

Wiping Times

15 + 30 + 60 seconds.

Controls

1. 1% Hospec general purpose neutral liquid detergent (Young's Detergents)/Kimcare Medical Wipes (Kimberly-Clark).
2. Sterets Alcowipe: 70% IPA (Seton Prebbles Ltd).
3. Sterile deionised water: Kimcare Medical Wipes (Kimberly-Clark).

Results are given in Table 1.

Exp. No.	Disinfectant/ Detergent	Mixing time (seconds)	Wiping time (seconds)	VC Surface	VC Wipe
1	200 ppm ClO_2	15	15	177	143
2	200 ppm ClO_2	15	30	36	14
3	200 ppm ClO_2	15	60	10	8
4	200 ppm ClO_2	30	15	800	300
5	200 ppm ClO_2	30	30	240	27
6	200 ppm ClO_2	30	60	29	26
7	300 ppm ClO_2	15	15	1240	330
8	300 ppm ClO_2	15	30	530	250
9	300 ppm ClO_2	15	60	160	140
10	300 ppm ClO_2	30	15	1450	900
11	300 ppm ClO_2	30	30	30	70
12	300 ppm ClO_2	30	60	20	10
13	1% Hospec		60	$7.3x10^4$	$4.3x10^5$
14	70% IPA		60	$1.9x10^4$	$3.7x10^4$
15	Deionised H_2O		60	$2.0x10^5$	$3.0x10^5$

TABLE 1

VC = Viable Count

Interpretation of Results

1. Washing/wiping with water, neutral detergent (1% Hospec), or alcohol (70% IPA) were ineffective

2. For the notional 200 ppm ClO_2 wipes the best results were obtained with a mixing time of 15 seconds and a wiping time of 60 seconds.

3. For the notional 300 ppm ClO_2 wipes the best results

were obtained with a mixing time of 30 seconds and a wiping time of 60 seconds.

4. Results for 200 ppm ClO_2 (notional) were surprisingly better than results for 300 ppm (notional), except for mixing times of 30 seconds combined with wiping times of at least 30 seconds.

5. A wiping time of 60 seconds achieved better results than a wiping time of 30 seconds, which in turn achieved better results than a wiping time of 15 seconds.

6. Both ClO_2 concentrations achieved good results after a wiping time of 60 seconds. The test surface was inoculated with 1×10^8 spores. After using the ClO_2 wipes, surface counts were reduced to 10 and 29 (200 ppm ClO_2) and to 160 and 20 (300 ppm ClO_2).

7. A wipe containing 200 or 300 ppm may be useful, as may mixing times of 15 or 30 seconds (or, clearly, any intermediate times). However, it is preferred that wiping times longer than 15 seconds are employed.

These results were obtained using bacterial spores. It is to be expected that a vegetative bacterium such as MRSA will be much more sensitive, so that lower ClO_2 concentrations and/or shorter mixing or wiping times may be effective against such bacteria.

Further experiments (2-4) were carried out using 41 gsm spunlace sheets comprised of 50.5% wood pulp and 49.5% PET. The sheets' dimensions were 160 mm x 180 mm x 0.36 mm. In

each experiment the wipes each contained 3 ml of Solution A (formulated as set forth below), made by treating a canister of 50 wipes with 150 ml of Solution A. Each wipe was activated with 1.5 ml of Solution B (formulated as set forth below) from a foam dispenser.

Solution A (Wipe)

Formulation:

Ingredients		Actual % w/w	Tolerance
1	Citric acid C.A.S. 77-92-9	0.50%	+/- 0.60-0.40%
2	Sorbic acid C.A.S.	0.005%	+/- 0.006-0.004%
3	Boric acid C.A.S. 10043-35-3	0.005%	+/- 0.006-0.004%
4	Trisodium citrate C.A.S. 68-04-02	0.25%	+/- 0.30-0.20%
5	Trisodium phosphate C.A.S. 10101-89-0	0.35%	+/- 0.45-0.25%
6	Glycerin C.A.S. 56-81-5	1.00%	+/- 1.10-0.90%
7	Benzotriazole C.A.S. 95-14-7	0.10%	+/- 0.15-0.05%
8	Sodium molybdate C.A.S. 10102-40-6	0.10%	+/- 0.15-0.05%
9	Sodium nitrate C.A.S. 7631-99-4	0.20%	+/- 0.25-0.15%
10	Preservative (Paramotol) C.A.S.	0.15%	+/- 0.20-0.10%
11	Deionised water C.A.S. 7732-18-5	Balance	Balance

Solution B (Foam)

Formulation:

Ingredients		Actual % w/w	Tolerance
1	Sodium chlorite (25% solution)	0.75%	+/- 0.85- 0.65%
2	Cocamidopropyl betaine	3.00%	+/- 3.10- 2.90%
3	Indicator/colour solution (Indicator is cosmetic yellow, No. 5, cl 19140 at 1% solution - 0.6%)	0.60%	+/- 0.07- 0.50%
4	Preservative (Euxyl K 100)	0.15%	+/- 0.20- 0.10%
5	Deionised Water (Purified) C.A.S. 7732-18-5	95.50%	+/- Balance

Experiment 2

A study was carried out to compare the effectiveness of (a) ClO_2 wipes in accordance with the invention (b) a 70% IPA wipe (c) a neutral detergent wipe and (d) a water wipe in removing and/or killing (1) B. subtilis spores, and (2) P. aeruginosa cells dried onto the insertion tube of a flexible endoscope.

Wipes were prepared fresh as required by squirting foam onto a wipe and then scrunching the wipe with the fingers to mix the reagents to form ClO_2.

EXPERIMENT 2

Test organisms

B. subtilis NCTC 10073 spores

A suspension containing approximately 10^8 spores/ ml was prepared by the method of Beeby & Whitehouse. A 1 in 10 dilution in sterile distilled water was prepared to produce a suspension containing approximately 10^7 spores/ ml.

P. aeruginosa NCTC 6749

A culture containing approximately 10^8 cells/ ml was prepared by inoculating a tube of nutrient broth and incubating for 18 h at 37^0 C.

Insertion tube used in Experiment 2

The insertion tube was 1 metre long, in good condition, with clear markings. The test site used was the 10 cm section between the 30 and 40 markings.

Test Method

1. Immerse a cotton-tipped swab into a suspension of spores or vegetative cells.
2. Inoculate entire surface area of test site with the suspension. Repeat several times. Regarding *B. subtilis* spores, assume that (1) the volume of inoculum = 0.1 ml, and (2) the mortality rate on drying out is zero. Hence the viable count of the inoculum = approximately 10^6 spores. Regarding *P. aeruginosa* cells, assume that (1) the volume of

inoculum = 0.1 ml, and (2) the mortality rate on drying out is 1 log. Hence the viable count of the inoculum = approximately 10^6 cells.

3. Place inoculated insertion tube across the top of an empty discard jar with the 10 cm test site resting over the centre of the jar. Allow inoculum to dry out (approximately 30 minutes).

4. Don pair of disposable plastic gloves.

5. Prepare a Wipe: ClO_2 (scrunch time = 15 sec), IPA, Hospec or water.

6. Wipe test site for the prescribed wipe time (30 sec) as follows: Wrap wipe loosely around the insertion tube and then wipe up and down the test site repeatedly.

7. Place the wipe in 20 ml of universal neutraliser in a Universal bottle. Vortex stir to release recovered spores/ cells (Test Suspension A).

8. Swab entire test site with a cotton-tipped swab. Dip swab into 10 ml of universal neutraliser in a Universal bottle and rotate swab against the inner wall of the bottle to release recovered spores/ cells. Repeat 10 times then break off cotton-tip of swab and leave in the neutraliser. Vortex stir to release recovered spores/ cells (Test Suspension B).

9. Prepare 5 serial deci-dilutions of Test Suspension A and Test Suspension B in diluent.

10. Inoculate 0.5 ml of each dilution onto a culture plate and spread using a plastic spreader. Incubate plates. Viable count.

11. Calculate $\log_{10}$ reductions achieved from the difference in the number of spores or cells inoculated onto the test site (approximately 10^6) and the number recovered after cleaning and/or disinfection.

Wipes used in Experiment 2

1. ClO_2 Wipe (scrunch time = 15 seconds).
2. 70% IPA wipe: Azowipe (Vernon Carus).
3. Hospec wipe: Kimberley Clark Medical Wipe immersed in 1% Hospec and then squeezed to remove excess solution.
4. Water wipe: Kimberley Clark Medical Wipe immersed in sterile water and then squeezed to remove excess water.

EXPERIMENT 2 - RESULTS

Exp	Test organism	Disinfectant/ detergent	Scrunch time (sec)	Wipe time (sec)	Viable Count (0.5 ml)	
					Surface	Wipe
1	*B. subtilis*	ClO2	15	30	0	0
2		ClO_2 (repeat)	15	30	0	0
3		70% IPA		30	5.0×10^2	2.7×10^3
4		1% Hospec		30	1.5×10^2	2.6×10^3
5		Water		30	3.0×10^1	2.5×10^3
6	*P. aeruginosa*	ClO_2	15	30	0	0
7		ClO_2 (repeat)	15	30	0	0
8		70% IPA		30	2	0
9		1% Hospec		30	6.2×10^3	8.0×10^4
10		Water		30	2.5×10^4	1.5×10^5

Table 2

Exp	Test organism	Disinfectant/ detergent	Total spores/ cells recovered	
			Surface[1]	Wipe[2]
1	*B. subtilis*	ClO_2	0	0
2		ClO_2 (repeat)	0	0
3		70% IPA	1.0×10^4	1.0×10^5
4		1% Hospec	3.0×10^3	1.0×10^5
5		Water	6.0×10^2	1.0×10^5
6	*P. aeruginosa*	ClO_2	0	0
7		ClO_2 (repeat)	0	0
8		70% IPA	4.0×10^1	0
9		1% Hospec	1.2×10^5	3.2×10^6
10		Water	5.0×10^5	6.0×10^6

Table 3

[1] Viable count in Table 1 x 20 (0.5 ml of 10 ml neutraliser plated out).

[2] Viable count in Table 1 x 40 (0.5 ml of 20 ml neutraliser plated out).

EXPERIMENT 2 - CONCLUSIONS

1. ClO_2 wipes were completely effective against both *B. subtilis* spores and *P. aeruginosa* cells. No spores or cells were recovered in duplicate experiments.
2. IPA wipes exhibited good activity against *P. aeruginosa* cells but did not eliminate all of the test cells - 40 viable cells were recovered from the test site on the insertion tube.

3. IPA wipes were ineffective against *B. subtilis* spores. IPA proved less effective than 1% Hospec or water which may be attributable to the coagulant properties of alcohol (fixing spores on the test site).

4. Wipes saturated with 1% Hospec were ineffective against either *B. subtilis* spores or *P. aeruginosa* cells.

5. Wipes saturated with water were ineffective against either *B. subtilis* spores or *P. aeruginosa* cells.

Experiment 3

EVALUATION OF THE EFFECTIVENESS OF ClO_2 WIPES IN KILLING/ REMOVING METHICILLIN RESISTANT STAPHYLOCOCCUS AUREUS (MRSA) DRIED ONTO A STAINLESS STEEL TEST SURFACE

Test Method

The following test method was used to evaluate the effectiveness of ClO_2 Wipes in killing/ removing test-organisms dried onto test surfaces. The test method involves the following steps:

1. Mark out an 18 inch (457.2 mm) square on the test surface.

2. Inoculate test surface with 4.5 ml of test organism suspension.

3. Spread inoculum over 18 inch (457.2 mm) square test area using a plastic spreader.

4. Allow inoculum to dry (30-60 minutes).

5. Don pair of disposable plastic gloves.

6. Prepare a ClO_2 Wipe using the prescribed scrunch time (15 seconds).

7. Wipe test area for the prescribed wipe time (30 seconds).

8. Place the ClO_2 Wipe in 20 ml of universal neutraliser in a universal bottle. Vortex stir to release organisms. (Test Suspension A).

9. Swab entire test area with a cotton-tipped swab. Dip swab into 10 ml of universal neutraliser in a universal bottle and rotate cotton-tip against the inner wall of the bottle to release organisms. Repeat 10 times. Finally, snap off cotton-tip into the neutraliser. Vortex stir to release organisms. (Test Suspension B).

10. Prepare 5 serial deci-dilutions of Test Suspension A and Test Suspension B in diluent.

11. Inoculate 0.5 ml of each dilution onto a culture plate and spread using a plastic spreader. Incubate plates. Viable count.

12. Calculate $\log_{10}$ reductions achieved from the difference in the initial inoculum and the number of test organisms recovered after cleaning/ disinfection with a ClO2 Wipe.

13. Repeat above using control wipes (70% IPA, 1% Hospec & sterile water).

Variables selected in Experiment 3

Test surface

A flat stainless steel laboratory bench.

Test organism

Methicillin Resistant Staphylococcus aureus (MRSA): a clinical isolate from the Royal Preston Hospital.

Inoculum

The test surface was inoculated with >10^9 bacterial cells: 4.5 ml of an overnight culture in Nutrient Broth.

Suspending fluid

Nutrient Broth

Scrunch time

15 seconds

Wipe time

30 seconds

Controls

1. 70% IPA wipe: Azowipe (Vernon Carus).
2. 1% Hospec general purpose neutral liquid detergent (Young's Detergents) / Kimcare Medical Wipe (Kimberly-Clark). The wipe was immersed in 1% Hospec and then squeezed with the fingers to remove excess fluid.
3. Sterile deionised water / Kimcare Medical Wipe (Kimberly-Clark). The wipe was immersed in water and then squeezed with the fingers to remove excess fluid.

Results

Exp	Disinfectant/ detergent	Mixing time (sec)	Wiping time (sec)	Viable Count	
				Surface	Wipe
1	ClO_2	15	30	0	0
2	ClO_2 (repeat)	15	30	0	0
3	70% IPA		30	5.5×10^4	9
4	1% Hospec		30	5.5×10^4	6.0×10^4
5	Deionised H_2O		30	5.7×10^4	5.9×10^4

Table 4

Exp	Disinfectant / detergent	Mixing time (sec)	Wiping time (sec)	Total number of organisms recovered	
				Surface[1]	Wipe[2]
1	ClO_2	15	30	0	0
2	ClO_2 (repeat)	15	30	0	0
3	70% IPA		30	1.1×10^6	3.6×10^2
4	1% Hospec		30	1.1×10^6	2.4×10^6
5	Deionised H_2O		30	1.1×10^6	2.4×10^6

Table 5

[1] Viable Count in Table 1 x 20 (0.5 ml of 10 ml neutraliser plated out).

[2] Viable Count in Table 1 x 40 (0.5 ml of 20 ml neutraliser plated out).

Interpretation of results

1. Wiping with a ClO_2 Wipe for 30 seconds was completely effective. No test organisms were recovered from either the test surface or the wipes in duplicate experiments.

2. Wiping the test surface with a 70% IPA wipe (Azowipe) for 30 seconds was ineffective. This could be due to:
(a) an exposure time of 30 seconds was not long enough to kill the MRSA
(b) the IPA evaporated off the test surface before the minimum exposure time required to kill the MRSA
(c) the volume of IPA on the wipe was insufficient to deal with the $>10^9$ MRSA dried onto the 18 inch test surface
(d) a combination of the above.

3. Only 360 test organisms were recovered from the Azowipe. This could be due to :
(a) entrapment of test organisms in the fibres
(b) incomplete/ slow neutralisation of the residual IPA on the wipe by the neutraliser
(c) a combination of the above

4. Wipes saturated with either 1% Hospec or sterile water were ineffective.

Experiment 4

This experiment was carried out to evaluate the effectiveness of ClO_2 Wipes in killing/ removing spores of *Bacillus subtilis var. niger* NCTC 10073 dried out for 24 h at room

temperature on a stainless steel test surface.

Test Method

1. Mark out a 12 inch (304.8 mm) square on the test surface.
2. Inoculate test surface with 1.0 ml of aqueous spore suspension.
3. Spread inoculum over 12 inch (304.8 mm) square test area using a plastic spreader.
4. Allow inoculum to dry out naturally at room temperature for 24 h.
5. Don pair of disposable plastic gloves.
6. Prepare a ClO_2 Wipe using the prescribed scrunch time (15 seconds).
7. Wipe test area for the prescribed wipe time (30 seconds).
8. Place the ClO_2 Wipe in 20 ml of universal neutraliser in a universal bottle. Vortex stir to release organisms. (Test Suspension A).
9. Swab entire test area with a cotton-tipped swab. Dip swab into 10 ml of universal neutraliser in a universal bottle and rotate cotton-tip against the inner wall of the bottle to release organisms. Repeat 10 times. Finally, snap off cotton-tip into the neutraliser. Vortex stir to release organisms. (Test Suspension B).
10. Prepare 5 serial deci-dilutions of Test Suspension A and Test Suspension B in diluent.
11. Inoculate 0.5 ml of each dilution onto a culture plate and spread using a plastic spreader.
12. Repeat above using a control wipe (a Medical Wipe saturated with sterile water).

13. Incubate plates. Viable count.

14. Calculate $\log_{10}$ reductions achieved using the ClO2 Wipe from the difference in viable count obtained using the ClO2 Wipe and the control wipe.

Variables selected in Experiment 4

Test surface

A flat stainless steel instrument tray.

Test organism

Bacillus subtilis var. niger NCTC 10073. A spore suspension was prepared by the method of Beeby & Whitehouse.

Inoculum

The test surface was inoculated with (a) 10^6 spores, and (b) 10^8 spores.

Suspending fluid

Deionised water.

Drying time

The inoculated instrument tray was allowed to dry out naturally at room temperature for 24 h in a dark cupboard.

Scrunch time

15 seconds.

Wipe time

30 seconds.

Control

1. Sterile deionised water / Kimcare Medical Wipe (Kimberly-Clark). The wipe was immersed in water and then squeezed with the fingers to remove excess fluid.

Results

Exp.	Inoculum (spores)	Disinfectant / detergent	Mixing time (sec)	Wiping time (sec)	Viable Count	
					Surface	Wipe
1	10^6	ClO2	15	30	0	0
2	10^6	Water	15	30	2.0×10^2	2.1×10^2
3	10^8	ClO2	15	30	4.8×10^2	1.3×10^2
4	10^8	Water	15	30	6.6×10^4	1.9×10^5

Table 6

Exp.	Inoculum (spores)	Disinfectant / detergent	Mixing time (sec)	Wipe time (sec)	Total number of spores recovered	
					Surface[1]	Wipe[2]
1	10^6	ClO2	15	30	0	0
2	10^6	Water	15	30	4.0 x 10^3	8.4 x 10^3
3	10^8	ClO2	15	30	9.6 x 10^3	5.2 x 10^3
4	10^8	Water	15	30	1.3 x 10^6	7.6 x 10^6

Table 7

[1] Viable Count in Table 1 x 20 (0.5 ml of 10 ml neutraliser plated out).

[2] Viable Count in Table 1 x 40 (0.5 ml of 20 ml neutraliser plated out).

Interpretation of results

1. Spores dried out for 24 h at room temperature on a stainless steel test surface were not easy to dislodge using a Medical Wipe saturated with deionised water. With the 10^6 inoculum the recovery was 4.0-8.4 x 10^3 spores leaving 2-3 $\log_{10}$ spores on the surface (assuming no mortality). With the 10^8 inoculum the recovery was 1.3 -7.6 x 10^6 spores leaving 1-2 $\log_{10}$ spores on the surface.

2. ClO_2 Wipes were effective in killing/ removing spores dried out for 24 h at room temperature on the stainless steel test surface. With the 10^6 inoculum, no spores were recovered

from either the surface or wipe which represents a 3-4 $\log_{10}$ reduction on both the surface and wipe. With the 10^8 inoculum, a 2-3 $\log_{10}$ reduction of spores was achieved on the surface and a 3-4 $\log_{10}$ reduction on the wipe.

Thus, the invention provides a decontamination system which can be prepared *in situ* and which provides bactericidal, fungicidal, virucidal, and sporicidal fabrics. The system is particularly useful for sterilising wipes and for the dressing of wounds and ulcers.

It is appreciated that certain features of the invention which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention which are, for brevity, described in the context of a single embodiment, may also be provided separately, or in any suitable combination. It is to be recognized that various alterations, modifications, and/or additions may be introduced into the constructions and arrangements of parts described above without departing from the ambit of the present invention. As used herein, the indefinite articles 'a' and 'an' connote 'one or more' unless the context requires otherwise.

CLAIMS

1. A decontamination system suitable for decontaminating items of medical equipment such as endoscopes, the system comprising:

(I) a plurality of pre-clean wipes comprising moist fabric members for wiping an item to be decontaminated;

(II) a two-part sterilant system comprising:

(a) a first part comprising a first reagent in a carrier medium; and

(b) a second part which is miscible with the first part and which comprises a second reagent in a carrier medium;

wherein the first reagent and the second reagent will react when mixed to provide a sterilising composition;

the first part being contained in a dispenser whereby it may be dispensed as a fluid, and the second part being absorbed or impregnated in a plurality of sterilising wipes each of which comprises a fabric member in a sealed container; and

(III) a plurality of rinse wipes, each rinse wipe comprising a moist, sterile, fabric member in its own sealed container.

2. A decontamination system according to claim 1, further comprising a record sheet for recording information concerning decontamination of an item of equipment.

3. A decontamination system according to claim 2, wherein each sterilising wipe is provided in its own sealed container and each of said containers carries on an outer surface a removable adhesive label which provides information about the contents of the container including at least one of: the lot

or batch number; the date of manufacture; a use-by or expiry date; and

wherein said record sheet includes a space for receiving said label.

4. A decontamination system according to claim 3, wherein said record sheet comprises a logbook which carries pre-defined spaces for receiving adhesive labels from each container for said sterilising wipes.

5. A decontamination system according to any preceding claim, wherein said first part includes a foam promoter and is contained in a trigger-operated foam dispenser.

6. A decontamination system according to any preceding claim, wherein at least one of said first part and said second part includes an indicator reagent that changes colour when the parts are mixed together.

7. A decontamination system according to claim 6, wherein said first part and said second part have a different pH and wherein the indicator reagent changes colour in response to a change in pH when the parts are mixed.

8. A decontamination system according to any preceding claim, wherein one of said first part and said second part comprises a solution containing sodium chlorite or sodium chlorate and the other comprises an acidic solution.

9. A decontamination system according to claim 8, wherein the acidic solution comprises a solution of citric acid, sorbic acid and boric acid.

10. A decontamination system according to any preceding claim, wherein said first part further comprises from 0.1 to 50% w/w of at least one foam promoter.

11. A decontamination system according to any preceding claim, wherein one of said first part and said second part further comprises from 0.1 to 50% w/w of a humectant.

12. A decontamination system according to any preceding claim, wherein when equal weights of said first part and the second part are mixed they provide a sterilising composition having a pH of from 4.5 to 6.5.

13. A decontamination system according to claim 8, wherein said first part comprises said solution of sodium chlorite or sodium chlorate.

14. A decontamination system according to any preceding claim, wherein said pre-clean wipes contain at least one surfactant.

15. A decontamination system according to any preceding claim, wherein said pre-clean wipes contain at least one enzyme for digesting or solubilizing organic deposits.

16. A decontamination system according to any preceding claim, wherein said rinse wipes include an agent for neutralising an active ingredient of the sterilant system.

17. A decontamination system according to any of claims 1-15, wherein said sterilant system will produce an oxidising

agent when the first and second parts are mixed, and wherein said rinse wipes contain an antioxidant to at least partly neutralise or reduce said oxidising agent.

18. A decontamination system according to claim 17, wherein said oxidising agent is ClO_2 and said antioxidant is sodium thiosulphate.

19. A decontamination system according to any preceding claim, wherein said rinse wipes further contain at least one component selected from: a sequestering agent, a lubricant, and a preservative.

20. A decontamination system according to any preceding claim, wherein each pre-clean wipe, each sterilising wipe, and each rinse wipe is provided in its own sealed sachet.

21. A decontamination system substantially as herein described with reference to or as shown in the drawings.

Application No: GB0410204.2 **Examiner:** Mr Chris Archer

Claims searched: 1-21 **Date of search:** 5 August 2004

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular reference
A	-	EP 0423817 A (BRISTOL-MYERS SQUIBB) see claim 1
A	-	WO 00/56203 A (STERIS) see whole document
A	-	US 2002/0006887 A (RADWANSKI) see whole document
A	-	EP 1340511 A (KABUSHIKI KAISHA SUNSEAL) see whole document
A	-	EP 1310263 A (CHEMISCHE FABRIK DR. WEIGERT) see whole document

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^{W} :

A5E; A5G; C5D

Worldwide search of patent documents classified in the following areas of the IPC^{07}

A01N; A61L; C11D

The following online and other databases have been used in the preparation of this search report

ONLINE: WPI, EPODOC, JAPIO