

User Manual

Long Stone International Co.

under

Council Medical Devices Directive (93/42/EEC) as updated directive 2007/47/EEC

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Device Name: Surgical scissors.

Approved by: Mr. Muhammad SAFDAR (Managing Partner)



Approval Signature

DISTRIBUTION LIST

Copy #	Copy Holder	Issue Date
1.	Director	15-06-2016

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Detailed Description of Device

Name: Surgical scissors SH/BL 14cm & Surgical scissors SH/BL 14cm with hook.

Finish: Satin & Powder Coating.

Instructions of Use

Surgical scissors are made of stainless steel type AISI-410 under standard ASTM F-899-84. They are used for cutting purpose.

Contents or Composition

ASTM Standard F-899-84

Carbon:	0.126%
Manganese:	0.514%
Phosphorus:	0.021%
Sulfur:	0.015%
Silicon:	0.275% max
Chromium:	13.503%
<u>Nickel:</u>	<u>0.101%</u>

Indication of Use

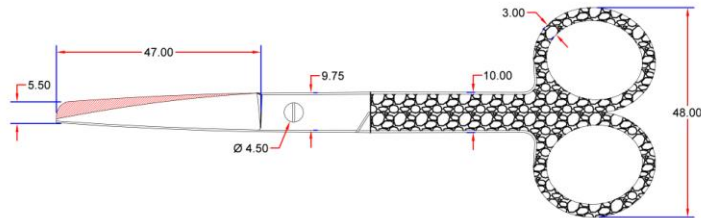
- Put away from the reach of uncontrolled person.
- Trained person must use the devices.
- Do not sterilize the instruments having the solution with Chloride ions. Sterilization solution must have the pH near to 6.0 - 7.0.
- For professional use only – disinfect before use.

Presentation of the Product

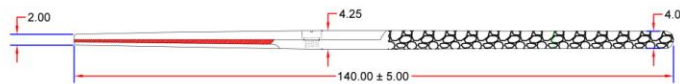
Device Name: Surgical Scissors SH / BL			
Size #:	140mm / 14cm		
Configuration	-----		
Drawing #:	-----		
Cataloge #:	20532		
Category #:	General Surgery		
Dimensions: All Dimensions are in Millimeters.			
Tolerance:	± 1.00 Unless Specified On The Drawing Itself		
Sheet: 1 of 1	Scale: 1 : 1		
1. Material:			
2. Hardness:			
3. FINISH: SATIN with colord Handle			
4. Marking: As Per Customer			
Drawn By:	Jawad Ali		
Reviewed By:			
Approved By:	Q.A Manager		
Dated:	22 July 2016		
Drawing Status:	FINAL		
REVISION			
No.	Dated:	Changed By:	Approved By:
PATH:			



Front View



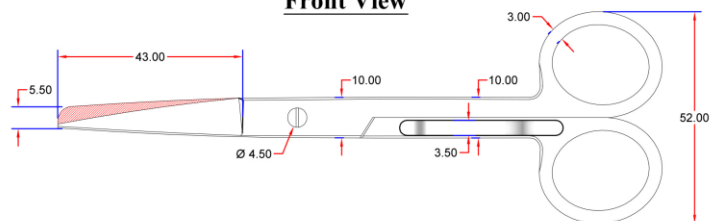
Side View



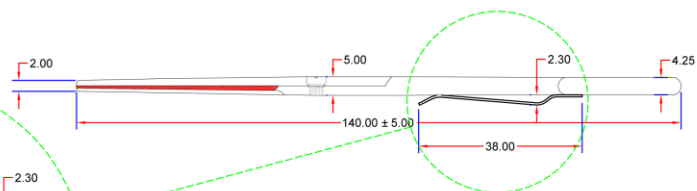
Device Name: Surgical Scissors SH / BLwith Hook			
Size #:	140mm / 14cm		
Configuration	-----		
Drawing #:	-----		
Cataloge #:	20520		
Category #:	General Surgery		
Dimensions: All Dimensions are in Millimeters.			
Tolerance:	± 1.00 Unless Specified On The Drawing Itself		
Sheet: 1 of 1	Scale: 1 : 1		
1. Material:			
2. Hardness:			
3. FINISH: SATIN			
4. Marking: As Per Customer			
Drawn By:	Jawad Ali		
Reviewed By:			
Approved By:	Q.A Manager		
Dated:	22 July 2016		
Drawing Status:	FINAL		
REVISION			
No.	Dated:	Changed By:	Approved By:
PATH:			



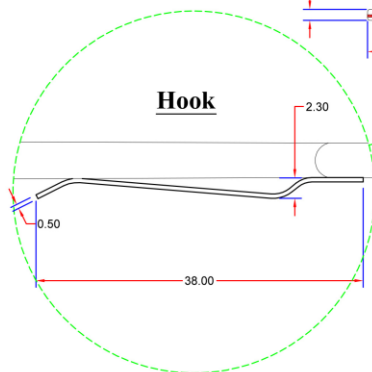
Front View



Side View



Hook



Precautions, restrictions, warnings, special cares

Methods of Proper Cleaning

Proper cleaning requires liquid soap/detergent, water and the use of a clean and disinfected scrub brush to remove all visible debris and residue.

All items should be scrubbed with a clean and disinfected scrub brush under running water.

Cleaning is not disinfection; disinfection is an entirely separate step. Different items are cleaned in different ways. This often depends on what the item is made of and how it was used.

NOTE: the cleaning step must be properly performed before an item can be disinfected. All items must be thoroughly rinsed and dried with clean cloth or paper towels prior to putting them into a disinfectant.

Methods of Proper Disinfecting

After proper cleaning, all reusable implements/tools must be disinfected by complete immersion in an appropriate disinfecting solution (see below, Appropriate Disinfectants).

The item must be completely immersed so that all surfaces, including handles, are soaked for the time required on the disinfectant manufacturer's label.

In general, U.S. Environmental Protection Agency (EPA) registered disinfectants require 10 minute immersion; isopropyl and ethyl alcohol require 5 minutes.

Remove items after the required time, using clean and disinfected tongs or gloves to avoid skin contact with the disinfectant solution.

If required by the instruction label, rinse thoroughly in running water.

Allow items to air-dry completely by placing them on top of a clean towel and covering them with another clean towel.

Thick foam cushioned buffers should have the moisture pressed out while in between disinfectant products are designed to destroy disease-causing microorganisms (pathogens) on non-living surfaces, such as those described in this document.

They are not appropriate for use on living skin and contact with skin should be avoided.

Appropriate salon disinfectants include the following:

(a) EPA-registered Hospital disinfectants with bactericidal, fungicidal and virucidal claims on the label. Instruments with powder coating color can be sterilized in simple mineral water up to temperature 110 °c for about 5 - 10 minutes.

(b) 10% bleach solution (1 part bleach to 9 parts water)

(c) Isopropyl alcohol, 70%-90% solution

(d) Ethyl alcohol, 70%-90% solution

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Individual Client Packs

Tools/instruments kept in individual packs must be properly cleaned and disinfected after each use.

If a client provides their own implements/tools, they must be properly cleaned and disinfected before use.

State rules require all tools and equipment to be disinfected before being reused, even if used by the same client! Improperly cleaned and disinfected implements may grow infection/disease-causing organisms before the client returns for their next visit, thereby increasing the risk of infection.

Never use air-tight bags or containers for storage as these can promote bacterial growth

Methods for Proper Storage of Tools and Equipment.

All properly cleaned, disinfected and dried implements/ tools must be stored in a sanitary manner.

A lined drawer is usually adequate, provided it is clean, contains only clean items and is properly labeled.

Store soiled or used items in a properly labeled, covered container separate from clean items. Never use airtight containers or zipper bags – these may promote bacterial growth!

Abrasive Files, Buffers and Electric File Bits After each use abrasive files, buffers, blocks or bits must be thoroughly cleaned by manually brushing with a clean and disinfected brush or by other adequate methods to remove all visible debris.

The sides of foam cushioned buffers, blocks or other abrasives should also be brushed after each use. After proper cleaning abrasives files, buffers and blocks are best disinfected by immersing in (or saturating with) 70-90% isopropyl or ethyl alcohol for 5 minutes.

Once electric bits have been thoroughly cleaned, they must be disinfected by complete immersion in an appropriate EPA registered disinfectant, as described in the next section. Any porous (absorbent) abrasive file, buffer, block, band, etc. that comes in contact with broken, damaged, infected or unhealthy skin or nails must be properly disposed of immediately, as described below.

Contact with Blood, Body Fluid or Unhealthy Conditions

If blood or body fluid comes in contact with any salon surface, the nail professional should put on a pair of clean protective, disposable gloves and use an EPA-registered Hospital liquid disinfectant or a 10% bleach solution to clean up all visible blood or body fluid.

In case of an accidental cut, clean with an antiseptic and bandage the cut. Disposable items, such as a cotton-tipped wood stick must be immediately double-bagged and discarded after use, as described at the end of this section.

Any non-porous instrument or implement that comes in contact with an unhealthy condition of the nail or skin, blood or body fluid, must be immediately and properly

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cleaned, then disinfected using an EPA-registered Hospital disinfectant as directed or a 10% bleach solution for 5 minutes.

Any porous/absorbent instrument that comes in contact with an unhealthy condition of the nail or skin, blood or body fluid must be immediately double-bagged and discarded in a closed trash container or biohazard box.