

Product data sheet

Trocar

1. Company data

1.1. Manufacturer:

Name Astra Tech AB
Address Box 14 SE-431 21 Mölndal
Country Sverige
Website www.astratech.com

1.2. Distributor:

Name Astra Tech A/S
Address Husby Allé 19
Phone no. + 45 4374 3377
Fax no. + 45 4371 7865
E-mail info.dk@astratech.com
Website www.astratech.dk

Quality management systems:

Manufacturer: ISO 9001, EN 46000

Distributor: ISO 9001, EN 46000

2. Product

2.1 Trade name Trocar

2.2. List of product range:

[See "Product range" \(if Excel file\)](#)

["Click here" \(if web based\)](#)

2.3. More information about the product

[See "More information" \(if Excel file\)](#)

["Click here" \(if web based\)](#)

3. Product components

(For sterile products including the item package/sterile barrier)

Cardboard: <input type="text" value="NO"/>	Paper: <u>Laminated paper</u>	Glass: <input type="text" value="NO"/>
Metal: <u>Stainless steel</u>	Latex: <input type="text" value="NO"/>	Cotton: <input type="text" value="NO"/>
Other: <u>Lacquer</u>		Organic: <input type="text" value="NO"/>

3.2. Plastics:

Types of plastic: _____ PVC:

If PVC, state plasticiser: DEHP (trocar cover) % of PVC: 25-30%

3.3. Heavy metals, chlorine, etc.:

Heavy metals: Types: _____

Chlorine bleached material: Recycled materials:

Are substances from the Environmental Agency's list of undesirable substances included? :

State substances: Note: By agreement with Sinerfa, this point takes effect only from 1 June 2003!!

4. Packaging components

(For sterile products **excluding** the item package/sterile barrier)

Cardboard:

Paper:

Glass:

Metal:

Latex:

Cotton:

Organic:

Other: _____

4.2. Plastics:

Types of plastic: _____

PVC:

If PVC, state plasticiser: _____

% of PVC: _____

4.3. Heavy metals, chlorine, etc.:

Heavy metals:

Types: _____

Chlorine bleached material:

Recycled materials:

State any substances from the Environmental Agency's list of undesirable substances: _____

Note: By agreement with Sinerfa this point takes effect only from 1 June 2003!!

5. CE marking

5.1. CE mark: No:

Yes:

Class: II a

6. Environmental information

6.1. Does a recognised env. label exist for the product area?

Yes:

No:

6.2. Does the product carry an environmental label?

No:

Yes:

Label: _____

6.3. Environmental management systems: (State recognised environmental management systems, if any)

Manufacturer: ISO 14001

Distributor: _____

7. Shelf life

Shelf life after date of manufacture / date of sterilisation:

8. Recommended storage and handling

State recommendations Dry environment, normal inhouse temperature

9. Recommendations for waste handling

Recommendation = X	Incineration	Landfill	Recycling	Recycling label
Product	x			
Item package	x			
Inner package			x	x
Transport packaging			x	x

Trocar

List of product range

Manufacturer product no.	Distributor product no.	EAN no. sales unit	Description	Size	Packaging unit	No. of packs per trsp carton	No. of cartons per pallet	Ste- rile
67225	67225	1 7392532 00432 2	Trocar	CH 8	1			*
67225	67225	50 7392532 00433 9	Trocar	CH 8	25	4	80	*
67228	67228	1 7392532 00434 6	Trocar	CH 10	1			*
67228	67228	50 7392532 00435 3	Trocar	CH 10	25	4	80	*
67230	67230	1 7392532 00436 0	Trocar	CH 14	1			*
67230	67230	50 7392532 00437 7	Trocar	CH 14	25	4	80	*
67231	67231	1 7392532 00438 4	Trocar	CH 18	1			*
67231	67231	50 7392532 00439 1	Trocar	CH 18	25	4	80	*

Note: EAN unit (first line) EAN ward box (second line)

Instructions:

There must be an EAN no. for each possible sales unit

The description may be the text of the distributor's invoice / delivery note

The size concept varies for different product areas, for instance S-M-L for absorbent pads, measurements, weight and ch for catheters, etc.

A packaging unit is for instance the number of items, rolls, cans, ml or similar.

Indicate sterile products by means of an *