

# Product data sheet

## Silicone catheter with 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 Silicone catheter

#### 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:  NO Paper: Laminated virgin paper Glass:  NO

Metal: Stainless steel Latex:  NO Cotton:  NO

Other: Silicone, bariumsulphate, lacquer Organic:  NO

#### 3.2. Plastics:

Types of plastic: \_\_\_\_\_ PVC:  YES

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

#### 3.3. Heavy metals, chlorine, etc.:

Heavy metals:  NO Types: \_\_\_\_\_

Chlorine bleached material:  NO Recycled materials:  NO

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

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

## Silicone catheter

### 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	Sterile
68361	68361		Flat silicone catheter w trocar	CH 14, 7mm	1			*
68361	68361		Flat silicone catheter w trocar	CH 14, 7 mm	25	4	80	*
68362	68362		Flat silicone catheter w trocar	CH 14, 10 mm	1			*
68362	68362		Flat silicone catheter w trocar	Ch 14, 10 mm	25	4	80	*
68367	68367		Silicone catheter w trocar	CH 10	1			*
68367	68367		Silicone catheter w trocar	CH 10	25	4	80	*
68368	68368		Silicone catheter w trocar	CH 14	1			*
68368	68368		Silicone catheter w trocar	CH 14	25	4	80	*
68369	68369		Silicone catheter w trocar	CH 18	1			*
68369	68369		Silicone catheter w 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 \*