0. FORWORD

This standard covers sterile Scalp vein (Winged needle) infusion set intended for single use primarily in humans. It does not give requirements or test method for freedom from biological hazards because international agreement upon the methodology and the pass/fail criteria is incomplete. Guidance on biological evaluation and tests are given in IS12572 (Part 1):1994/ISO10993-1: 1992 'Biological evaluation of medical devices : Part 1 Guidance on selection of tests (first revision)’ and it is suggested that manufacturers take this guidance into account when evaluating products. Such an evaluation should include the effects of the process whereby the infusion sets are sterilized. However, national regulations may exist in some countries, and these will override the guidance in IS 12572 (Part 1): 1994/ISO 10993-1:1992.

Plastic materials to be used for the construction of Scalp vein infusion set are not specified, as their selection will depend to some extent upon the design, process of manufacture and method of sterilization employed by individual manufacturers. The materials should be compatible with injection fluids. (see IS 10654).

1. Scope:

This Draft Indian Standard specifies requirement for Scalp Vein Infusion Set supplied in the sterile condition and intended for single use.

2. REFERENCE:

2.1 The Indian Standards and ISO Standards are necessary adjuncts to this standard


IS 3234(Part 1) :1986/ISO 594-1: 1986 Conical fitting with 6%(luer) taper for syringes, needle and certain other medical equipment- Part 2: Lock fittings


ISO 6009 Hypodermic needle for single use and colour coding for identification.
3. NOMENCLATURE

The nomenclature for components of Scalp Vein infusion set for single use is shown in figure 1

Nomenclature for needle point is shown in figure 2.

4. CLEANLINESS:

When inspected by normal or corrected to normal vision without magnification the surface of the Infusion set shall appear free from particle and extraneous matter.

When examined under x 2.5 magnification the adopter socket shall appear free from particle and extraneous matter (see IS 10654).

5. LIMITS FOR ACIDITY AND ALKALINITY:

When determined with a laboratory pH meter and using a general purpose electrode, the pH value of an extract prepared in accordance with Appendix A shall be within one unit of pH of that of the control fluid.

6. LIMITS FOR EXTRACTABLE METALS:

When tested by a recognized microanalytical method, for example by an atomic absorption method, an extract prepared in accordance with annex A shall, when corrected for the metals content of the control fluid, contain not greater than a combined total of 5 mg/l of lead, tin, zinc and iron. The cadmium content of the extract shall, when corrected for the cadmium content of the control fluid, be lower than 0.1 mg/l (see IS 10654).

7. SIZE DESIGNATION:

The size of infusion set shall be designated by the following:

a) the nominal outside diameter of the needle tube expressed in millimetres;
b) the nominal length of the needle tube, expressed in millimetres.

The size shall be referred to as the designated metric size” and shall be expressed in millimetres for

Example
0.8 x 40 (see IS 10654).

8. COLOUR CODING:

The nominal outside diameter of needle tube shall be identified by colour coding. The colour coding can be applied to the unit container and / or part of the infusion set such as the wing or the sheath.
9. ADOPTER:

The conical socket of the adopter shall be in accordance with IS 3234(Part 1): 1986/ISO 594-1:1986 Conical fitting with 6%(luer) taper for syringes, needle and certain other medical equipment- Part 1 General requirement.

10. WING:

Wing shall be made either of pigmented or unpigmented material, if pigmented, the colour shall be in accordance with Table 1.

11. SHEATH:

A separate needle sheath shall be provided, it shall be made either of pigmented or of unpigmented material, if pigmented, the colour shall be in accordance with Table 1.

Table 1:

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Nominal O.D of needle</th>
<th>Colour</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.4</td>
<td>Medium grey</td>
</tr>
<tr>
<td>2</td>
<td>0.45</td>
<td>Brown</td>
</tr>
<tr>
<td>3</td>
<td>0.5</td>
<td>Orange</td>
</tr>
<tr>
<td>4</td>
<td>0.55</td>
<td>Red</td>
</tr>
<tr>
<td>5</td>
<td>0.6</td>
<td>Blue</td>
</tr>
<tr>
<td>6</td>
<td>0.7</td>
<td>Black</td>
</tr>
<tr>
<td>7</td>
<td>0.8</td>
<td>Green</td>
</tr>
<tr>
<td>8</td>
<td>0.9</td>
<td>Yellow</td>
</tr>
<tr>
<td>9</td>
<td>1.1</td>
<td>Cream</td>
</tr>
<tr>
<td>10</td>
<td>1.2</td>
<td>Pink</td>
</tr>
<tr>
<td>11</td>
<td>1.4</td>
<td>Red Violet</td>
</tr>
</tbody>
</table>

12. EXTENTION TUBE:

Extension tube shall be made of flexible material. Tolerance of length of the tube shall be ± 5%( over the length specified by the manufacturer).

13. NEEDLE TUBE:

The needle shall be made of tubing in accordance with ISO 9626.
13.1 NEEDLE LENGTH:

Preferred needle length may be 19 mm ( ¾”), However manufacturer can vary the length to suit specific requirements. A general tolerance on specified length ( up to 25 mm ) shall be ( +1, -2mm).

13.2 FREEDOM FROM DEFECTS:

When examined by normal or corrected vision the needle tube shall appear straight and have regular cross section and wall thickness ( see IS 10654).

13.3 LUBRICATION :

If the needle tube is lubricated, the lubricant shall not be visible under normal or corrected vision as droplets of fluid on the outside or inside surfaces of the needle tube ( Ref IS 10654).

*NOTE* An acceptable lubricant, is polydimethylsiloxane complying with a national or European pharmacopoeia

14. NEEDLE POINT :

When examined under x 2.5 magnification the needle point shall appear sharp and free from feather edges, burrs, and hooks ( see IS 10654).

The designation of needle point dimensions and the nomenclature used to describe the dimensions and features shown for information in figure 2. The needle points shown are of configurations commonly manufactured: other configurations may be equally satisfactory. It may not be necessary to use all the dimensions when describing the point configuration.

15. PERFORMANCE

15.1 BOND BETWEEN WING AND NEEDLE TUBE :

The union of the wing and needle tube shall not be broken by the minimum force give below

  10 N when testing needle of nominal outside diameter less than 0.6 mm.
  15 N when testing needle of nominal outside diameter 0.6 mm or greater.

15.2 BOND BETWEEN WING AND EXTENTION TUBE:

The union between wing and extension tube shall not be loosened when a force of 15 N is applied in pulling direction for 15 seconds.
15.3 BOND BETWEEN EXTENTION TUBE & ADOPTER:

The union between adopter and extension tube shall not be loosened when a force of 15 N is applied in pulling direction for 15 seconds.

16. PACKING

16.1 PRIMARY CONTAINER:

Each infusion set shall be sealed in primary container. The material and design of this container shall be such as to ensure that the colour coding of the contents is visible.

The material of the container should not have detrimental effects on the contents. The materials and design of this container should be such as to ensure:

a) the maintenance of sterility of the contents under dry, clean and adequately ventilated storage conditions;

b) the minimum risk of contamination of the contents during removal from the container;

c) adequate protection of the contents during normal handling, transit and storage;

d) that once opened, the container cannot be easily resealed, and it should be obvious that the container has been opened. (See IS 10654).

16.2 SECONDARY CONTAINER:

One or more primary containers shall be packaged in a secondary container.

The secondary container should be sufficiently robust to protect the contents during handling, transit and storage.

One or more secondary containers may be packaged in storage and/ or a transit container. (see IS 10654)

17. LABELING:

17.1 PRIMARY CONTAINER:

The primary container shall be marked with at least the following information:

a) a description of the contents, including the designated metric size in accordance with clause 7;

b) the word “STERILE”;

c) the lot number, prefixed by the word “LOT”;

d) the name or trade-mark or trade-name or logo of the manufacturer or supplier.
17.2 SECONDARY CONTAINER:

The secondary container shall be marked with at least the following information:

a) a description of the contents, including the designated metric size in accordance with clause 7 and the number;
b) the word “STERILE”;
c) the words “FOR SINGLE USE” or equivalent (excepting the term “disposable”);
   NOTE The symbol given in annex B may additionally be given.
d) a warning to check the integrity of each primary container before use;
e) the lot number, prefixed by the word “LOT”;
f) the date of sterilization (month and year);
   NOTE The date of sterilization may be incorporated in the first several digits of the lot number.
g) the name and address of the manufacturer or supplier;
h) information for handling; storage and transportation.

17.3 STORAGE CONTAINER:

If secondary containers are packed in a storage container, the storage container shall be marked with at least the following information:

a) a description of the contents, including the designated metric size in accordance with clause 7 and the number;
b) the lot number, prefixed by the word “LOT”;
c) the word “STERILE”;
d) the date of sterilization;
e) the name and address of the manufacturer or supplier;
f) information for handling, storage and transportation of the contents.
Figure 2—Designation of dimensions and nomenclature of needlepoint geometry (see Clause 12)

Key:
- $d_1$: Outside diameter of needle tube
- $d_2$: Inside diameter of needle tube
- $A$: Polled length
- $B_1$: Primary bevel nominal length $B_1 = (A - C_1)$
- $B_2$: Right primary bevel length
- $C_1$: Left primary bevel length
- $C_2$: Secondary bevel nominal length
- $C_3$: Right secondary bevel length
- $C_4$: Left secondary bevel length
- $\alpha$: Primary bevel angle
- $\beta$: Secondary bevel angle
- $\beta_1$: Tip angle
- $\beta_2$: Right secondary bevel rotation angle
- $\beta_3$: Left secondary bevel rotation angle
- $\gamma$: Combined secondary bevel angle

View showing variant when primary bevel intersects needle tip

Needle rotated by angle $\gamma$
Appendix A
(Clause 5)
Method for preparation of extracts

A.1 Principle

The infusion set is immersed in water in order to extract soluble components.

A.2 Apparatus and Reagents

A.2.1 Freshly prepared distilled or deionised water, of grade 3 in accordance with ISO 3696

A.2.2 Selection of laboratory borosilicate glassware.

A.3 Procedure

A.3.1 Immerse 05 Infusion sets in 250 ml of water (A.2.1) in a suitable container made from borosilicate glass (A.2.2).

Ensure that all surfaces of the infusion sets, including the inside of the surfaces of the needle tube, are in contact with the water. Maintain the water at a temperature of 37 +3°C for 60 ± 2 min. Remove the infusion sets and ensure that all water from the inside and outside surfaces of the infusion sets is returned to the container.

A.3.2 Prepare the control fluid by following the procedure given in A.3.1 but omitting the infusion sets.
Dear Madam(s)/Sir(s),

Please find enclosed the following documents:

**DOC NO:** MHD 13(0097)
**TITLE:** Draft Indian Standard for STERILE SINGLE USE SCALP VEIN (WINGED NEEDLE) INFUSION SET

Kindly examine the draft Indian Standard and forward your views stating any difficulties which you are likely to experience in your business or profession, if this is finally adopted as National Standards.

**Last date for comments:** 11-08-09

Comments if any, may please be made in the format enclosed and mailed to the undersigned at the above address. In case no comments are received or comments received are of editorial nature, you will kindly permit us to presume your approval for the above document as finalized. However, in case of comments of technical in nature are received then it may be finalized either in consultation with the Chairman, Sectional Committee or referred to the Sectional committee for further necessary action if so desired by the Chairman, Sectional Committee. This document is available on BIS web site www.bis.org.in.

Thanking you,

Yours faithfully,

(Rahul Kumar)

Encl: As Above
Scientist’s & Head (MHD)
E-Mail – hmhd@bis.org.
FORMAT FOR SENDING COMMENTS ON BIS DOCUMENTS
(Please use A4 size sheet of paper only and type within fields indicated. Comments on each clauses/sub-clauses/table/fig. etc be started on a fresh box. Information in Column 5 should include reasons for the comments and suggestions for modified wording of the clauses when the existing text is found not acceptable. Adherence to this format facilitates Secretariat’s work)

DOC NO: MHD 16(0097)
TITLE : Draft Indian Standard for STERILE SINGLE USE SCALP VEIN (WINGED NEEDLE) INFUSION SET

LAST DATE OF COMMENTS: **11 08 09**

NAME OF THE COMMENTATOR/ORGANIZATION: _______________________

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Clause/Sub-clause para/table/fig.</th>
<th>Commentator Orgn (Abbreviation)</th>
<th>Comments</th>
<th>Justification &amp; Proposed change</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>